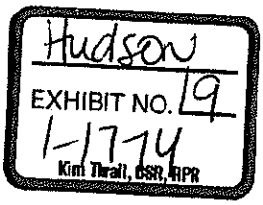
EXHIBIT 41

BARD
PERIPHERAL
VASCULAR

Recovery Filter Migration
Remedial Action Plan
SPA-04-04-02
April 21, 2004



BARD
PERIPHERAL
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Closed
6/11/2004

Recovery Filter Migration
Remedial Action Plan
SPA-04-04-02
April 21, 2004

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Remedial Action Plan
SPA-04-04-02

To: Doug Uelmen

From: Pete Palermo

Date: June 11, 2004

Subject: **Remedial Action Plan**
BPV Recovery Filter – Migration (SPA04-04-02)

The above action plan was reviewed by the Corporate PAT on:

Date Reviewed: April 22, 2004
Corporate PAT Reviewers:
Corporate Law: D. Passero
Corporate RA: B. Barry
Corporate Medical: J. Lehman/D. Ciavarella
Corporate Ops: J. Cherry
Corporate QA: P. Palermo

Corporate PAT Recommendations:
A conference call was established with D. Uelmen, Division VP Quality Assurance, representing the BPV Division PAT and the Corporate PAT members on 4/22/04. The Corporate PAT concurs with the Division PAT recommendations with modifications to the action plan.

Revisions to the Division action plan were received by Corporate QA on 5/21/04.

Corporate PAT Recommendations were presented to Vice President, Regulatory Sciences:

Presented By: P. Palermo
Date Presented: April 24, 2004

Decision of the Vice President, Regulatory Sciences:
Action plan presented at 4/22/04 teleconference. VP Regulatory Sciences concurs with recommended Action plan.

Pete Palermo/BK
Peter Palermo
Vice President, Quality Systems

Cc: C. Ganser
J. Weiland
J. McDermott
Corporate PAT

BARD
PERIPHERAL
VASCULAR

Division Product Assessment Team
Bard Peripheral Vascular Division
Remedial Action Plan
SPA 04-04-02

L. DeCant — V.P. R&D — 4/21/04 — 4/28/04
5/19/04

M. Edwards — V.P. R.A. / C.A. — 4/21/04 — 4/28/04
5/19/04

J. McDermott — President For John McDermott — 4/28/04 — 4/21/04
5/19/04

K. Shifrin — Michael C. Warren V.P. Marketing For Kevin Shifrin — 4/21/04 — 4/28/04
5/19/04

D. Uelmen — V.P. QA — 4/21/04 — 4-28-04
5/18/04

BARD
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VASCULAR

Remedial Action Plan
Bard Peripheral Vascular Division
SPA-04-04-02
April 21, 2004

I. Product Description and Intended Use

a. The Recovery Filter consists of twelve shape-memory nitinol wires emanating from the central nitinol sleeve. These twelve wires form two levels of filtration. The legs provide a lower level of filtration and fixation to the caval wall. The arms provide the upper level of filtration and help center the filter in the vessel. The Recovery Filter is intended to be used in vena cava circular diameters up to 28 mm.

The Recovery Filter Delivery System consists of a 7 French I.D. introducer sheath and dilator, the Recovery Filter, a storage tube with saline infusion port, and a pusher system. The Recovery Filter is packaged pre-loaded within the delivery storage tube.

b. The Recovery Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted in the inferior vena cava (IVC). The Recovery Filter has the additional feature of being able to be percutaneously removed after implantation. The Recovery Filter may be used as a permanent filter or be implanted temporarily to treat the temporary risk of pulmonary embolism. The Recovery Filter has the following indications for placement:

1. Pulmonary thromboembolism when anticoagulants are contraindicated.
2. Failure of anticoagulant therapy in thromboembolic disease.
3. Emergency treatment following massive pulmonary embolism where the anticipated benefits of conventional therapy are reduced.
4. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

II. Manufacturer / Distributor

c. The product is manufactured by the Bard Glens Falls Operation, Queensbury, NY and distributed by the Bard Peripheral Vascular, Inc. through the Bard Distribution Center, Covington, GA.

III. Identification of the Problem:

a. On 4/14/04, a telephone message was left with BPV Field Assurance from Redacted of Redacted Risk and Compliance in Redacted She had been "notified by a medical examiner from another county about a patient who expired and the ME believed that the cause of death was an IVC filter that migrated." (Complaint Report # 5922, attached).
b. The MedWatch report issued by the hospital indicated that the Recovery Filter was placed in the patient for deep vein thrombosis. The filter had been placed approximately 13 days prior to death, Redact The patient was then released from the hospital on [redacted] and expired on Redact
c. As of 4/14/04 there had been six previous instances reported to BPV Field Assurance where the filter had migrated >2cm (Patient Comparison Matrix, attached).
    1. Patient asymptomatic, the filter was removed without incident.
    2. Patient asymptomatic, the filter was removed without incident.
    3. A 4 cm cephalad move, the filter remains in place.
    4. Patient reported shortness of breath and light headedness. Surgical removal of the filter and clot without intraoperative or postoperative difficulties.
    5. The interventional radiologist released the filter tilted 50 degrees with legs twisted. During an attempt to retrieve it that used a method contraindicated in the IFU, the filter migrated into the right atrium.
    6. The inferior vena cava filter with large filter burden was dislodged by a large thrombus and migrated to the heart resulting in patient's death.
d. The subject product lot number is 07LN2037.
    1. The lot contained 37 units.
    2. The subject product DHR was reviewed. There were no issues associated with the following:
        i. Sub-assemblies
        ii. MRRs (material review reports)
        iii. Raw material testing (nitinol wire)
        iv. Manufacturing processes
        v. Quality Control Inspections
        vi. A review of the complaint history records show no other complaints associated with this lot.
e. There have been approximately 8,200 Recovery Filter units distributed since the product was released in April 2003.

f. On April 16, 2004;
   1. The Medical Examiner, Dr. Banner, and the Interventional Radiologist, Redacted were contacted to obtain as much additional information as possible concerning the case (Investigation Summary, attached).
   2. The Division PAT met to discuss the issue and agreed to immediately assign the necessary resources to aggressively complete an investigation into the incident.
   3. Bard Corporate Executive Management was notified.

IV. Medical Evaluation:

a. See Heath Hazard Evaluation report attached.

V. Number of units and lots involved:

a. There have been approximately 8,200 Recovery Filters distributed as of April 14, 2004.

VI. Distribution of Units

a. Recovery Filters are being distributed in the United States, United Kingdom, Canada and Australia.

VII. Action Plan:

a. On April 14, 2004, after the notification of the migration in Redact from Redacted Risk & Compliance, the Recovery Filter was placed "On Hold" pending completion of this action plan.
b. The Divisional Product Assessment Team convened on April 16, 2004, to develop a Recovery Filter remedial action plan based on R-002 to guide this investigation.
c. On April 19, 2004, members of the Division PAT met with Redacte Dr. Banner and Redacted Risk Management to inquire about information regarding this incident.
d. The team met again on April 21, 2004 to discuss all information obtained in order to bring resolution to this issue. The following key facts were identified by the Product Assessment Team as a result of this meeting:
   1. Based on the information supplied by Redacted and Dr. [redacted] the filter was properly placed.
   2. Clot formation was antemortem (Investigation Summary, attached).
   3. Thromboembolus measured approximately 3 cm by 5 cm (Investigation Summary, attached).

4. There were no design or manufacturing defects found to be associated with the filter.
5. The Division Product Assessment Team (including the Medical Affairs Consultant) has reviewed data found within the Maude data base and IMS sales data (attached) in support of this remedial action plan. The limitations of the data are well known and identified in the Health Hazard Evaluation (attached). The Division PAT accepts the conclusion found on page one of the HHE.
6. The Division PAT has reviewed the migration rate for Recovery Filters comparing the data prior to receiving 510(k) concurrence for the recovery indication (April through July 2003) with post recovery indication data (August 2003 to present). We conclude that although all migration issues occurred after August 2003, there was an insufficient quantity of product in the market prior to August 2003 (826 units) to provide a meaningful comparison.

e. The Hospital MDR attached (based on verbal information) was filed on April 13, 2004 (Mfr. Report Number 230038-2004-0002, attached).
f. The BPV Product Assessment Team has concluded that the Recovery Filter captured a large embolic load with resulting increase in venous pressure that lead to inferior vena cava dilatation greater than 28 mm resulting in migration.
g. The Division PAT has defined migration as vena cava filter movement >2 cm from the deployed location (as defined in the Journal of Vascular and Interventional Radiology (2001) Vol. 12:137-141).
h. The Division PAT has defined massive clot as: thrombus of sufficient size to cause the internal diameter of the inferior vena cava to distend beyond the maximum size indicated for the vena cava filter in the Instruction for Use.
i. The migration categories have been updated to address death due to migration and migration due to causes other than thromboemboli.
j. The following migration categories have been identified to aid in risk assessment:
    1. Migration resulting in patient death related to thromboemboli.
    2. Migration resulting in death unrelated to thromboemboli.
    3. Surgical intervention after successful deployment.
    4. Surgical intervention as a result of an unsuccessful deployment.
    5. Minimally invasive interventions required after a successful deployment.

6. Minimally invasive interventions required after an unsuccessful deployment.
7. No intervention required after a successful deployment.
8. No intervention required after an unsuccessful deployment.

k. Migration resulting in patient death requires the Division PAT to convene immediately and initiate an investigation per R-002. If the cause of the event is an anticipated adverse event and the occurrence rate does not exceed accepted frequency, the product will continue to be marketed during the investigation. If at any time during the investigation, data shows the cause of the event to be unrelated to massive thromboemboli, the Division PAT shall immediately review all data gathered during the investigation and re-evaluate the status of the product as the investigation is completed per RA-002 (massive thromboemboli as defined above in section VII.h).

l. Vena Cava Filter Adverse Event frequency rates will be reviewed on a quarterly basis. Rates will be obtained from: Maude, IMS, Lexis / Nexis and other medical literature as identified during the search. A comparison of the Recovery Vena Cava Filter to all other Vena Cava Filters will be completed. Frequency rates will be compared to assure that adverse events associated with the Recovery Filter are not occurring with excess frequency. Although this report will be an important element in deciding product status, the Division PAT realizes that comparative attempts to assess similar events via the above mentioned information sources do not yield reliable quantitative estimates for the following reasons:
    1. Potential under-reporting (Maude).
    2. Potential over-reporting (IMS, sales data can only be roughly estimated).
    3. Inadequate description of events in the Maude database, resulting in potential misclassification.
    4. Very low frequency of events
    5. High variability in event rates and sales rates across devices and time periods

m. A comparison of this data will be completed on a quarterly basis and provided to Division Management with executive responsibility during Management Review. This comparative information will be maintained for use in frequency rate comparisons for future Vena Cava Filter action plans. If the data results in a change of the frequency category from "remote" to "occasional" (reference the Hazard Risk Assessment Matrix found in appendix B of RA-STD-002 Rev. 08) the Division PAT will reconvene to review the issue and develop a remedial action plan.

n. The product was removed from Hold status on April 25, 2004 upon receipt of a Health Hazard Evaluation provided by Redact Redacte. Distribution commenced on April 26, 2004.

o. An independent clinician review panel will be convened during Q2 2004. The panel will consist of Interventional Radiologists and Vascular Medicine Specialists to discuss DVT and its treatment. J. Hudnall will identify the clinicians and develop the agenda by the end of May and schedule a June meeting.
p. Labeling will be updated to clarify issues concerning migration including the severity of the consequences. M. Edwards will complete this task by the end of May (please see the attached draft of IFU changes).
q. Obtain the final Pathology Report (May 11, 2004).

VIII. Product Correction:

a. There has been no device design or manufacturing problem that was identified as contributing to the patient death associated with the Complaint Report (attached) of this investigation. No field action is recommended at this time.

Bard Limited
Forest House, Tilgate Forest Business Park
Brighton Road, Crawley
West Sussex RH11 9BP
England, U.K.

BARD

To: Shari Allen

From: David Marshall

Date: 1st March 2005

Subject: **Recovery Filter**

As European Authorised Representative for C. R. Bard Inc., I confirm that I have acted on behalf of Bard Peripheral Vascular Division (BPV) with respect to the Recovery Filter as follows:

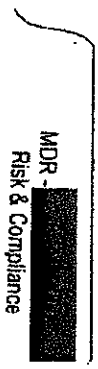
I have received notification from BPV regarding changes to the product IFU, generated in the light of worldwide clinical experience and reviewed and agreed by FDA. I understand these changes to have been developed in part as a result of adverse incidents reported in the USA market. Understanding that such adverse incidents, occurring outside the EU and resulting in what might be considered to be a corrective action by the manufacturer, might also be considered to require a Vigilance reporting obligation within the EU, I have consulted with MHRA. The MHRA Product Specialist has reviewed and agreed the IFU changes, understands the rationale for their development and has received and has reviewed worldwide statistics for adverse incidents concerning this product. The MHRA are satisfied with BPV's diligence with regard to these issues and has approved the process for informing Doctors, which has been completed to the Agency's satisfaction.

In light of this comprehensive consultation process with the relevant European Competent Authority I believe that we have adequately discharged any obligation to notify adverse events occurring outside Europe for this product to date. I know that BPV will continue to monitor whether any further such notification might be appropriate in future.

Yours sincerely

David Marshall
Director of Regulatory Affairs & Quality Assurance
Bard Europe

Telephone: 01293 527888 • Fax: 01293 552428
Registered Office as above Registered in England No. 939600


MDR -
Risk & Compliance

Form Approved: OMB No. 0910-0291, Expires: 03/31/06
See OMB statement on reverse.

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 of 2

MFR Report #

UF/Importer Report # 2300038-2004-0002

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier: Redacted (in confidence)
2. Age at Time of Event: or Date of Birth: Redacted
3. Sex: ☒ Female ☐ Male
4. Weight: lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☒ Adverse Event and/or ☒ Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - ☒ Death: Redacted (mm/dd/yyyy)
   - ☐ Life-threatening
   - ☐ Hospitalization - Initial or prolonged
   - ☐ Disability
   - ☐ Congenital Anomaly
   - ☐ Required intervention to Prevent Permanent Impairment/Damage
   - ☐ Other:
3. Date of Event (mm/dd/yyyy): Redacted
4. Date of This Report (mm/dd/yyyy): 04/13/04
5. Describe Event or Problem

Contacted by Medical Examiner of Montcalm County related to patient discharged from hospital on Redacted Patient had IVC filter placed after developing DVT's prior to discharge. Patient's initial results of post mortem reveals IVC filter in right ventricle causing perforation. Medical examiner reported patient had fatal complication of filter. Caught large burden of clot dislodged and perforated right ventricle.

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney dysfunction, etc.)

Admitted on Redacted for Subarachnoid Hemorrhage

C. SUSPECT MEDICATION(S)

1. Name (Give labeled strength & manufacturer, if known)
   #1
   #2
2. Dose, Frequency & Route Used
   #1
   #2
3. Therapy Dates (if unknown, give duration) from/to (or best estimate)
   #1
   #2
4. Diagnosis for Use (Indication)
   #1
   #2
5. Event Abated After Use Stopped or Dose Reduced?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply
6. Lot # (if known)
   #1
   #2
7. Exp. Date (if known)
   #1
   #2
8. Event Reappeared After Reintroduction?
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply
9. NDC# (For product problems only)
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

D. SUSPECT MEDICAL DEVICE

1. Brand Name: CR Bard
2. Type of Device: Recovery Filter Femoral Set
3. Manufacturer Name, City and State: Bard Peripheral Vascular Tempe Az
4. Model #: RFA49F
   Catalog #:
   Lot #: 0711W2037
   Expiration Date (mm/dd/yy): 02/07
   Serial #:
   Other #:
5. Operator of Device: ☒ Health Professional ☐ Lay User/Patient ☐ Other:
6. If Implanted, Give Date (mm/dd/yy): Redacted
7. If Explanted, Give Date (mm/dd/yy):
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? ☐ Yes ☒ No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) ☐ Yes ☒ No ☐ Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

E. INITIAL REPORTER

1. Name and Address: Redacted
2. Health Professional? ☒ Yes ☐ No
3. Occupation: RN
4. Initial Reporter Also Sent Report to FDA? ☒ Yes ☐ No ☐ Unk.

PLEASE TYPE OR USE BLACK INK

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

FORM FDA 3500A (9/03)

Medication and Device Experience Report

(Continued)

Refer to guidelines for specific instructions.

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

FOR FDA USE ONLY

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F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. Check One: [X] User Facility [ ] Importer
2. If Importer Report Number: 2500238-2004-00002
3. User Facility or Importer Name/Address: Redacted
4. Contact Person: Redacted
5. Phone Number: Redacted
6. Date User Facility or Importer Became Aware of Event (mo/day/yr): 04/13/04
7. Type of Report: [X] Initial [ ] Follow-up #
8. Date of This Report (mo/day/yr): 04/15/04
9. Approximate Age of Device:
10. Event Problem Codes (Refer to coding manual): Patient Code: 1907 - - Device Code: 1236 - 1395 -
11. Report Sent to FDA? [X] Yes 04/15/04 (mo/day/yr) [ ] No
12. Location Where Event Occurred: [ ] Hospital [ ] Home [ ] Nursing Home [ ] Outpatient Treatment Facility [ ] Outpatient Diagnostic Facility [ ] Ambulatory Surgical Facility [ ] Other: Unknown (Specify)
13. Report Sent to Manufacturer? [X] Yes 04/14/04 (mo/day/yr) [ ] No
14. Manufacturer Name/Address: C R Bard Tempe AZ

G. ALL MANUFACTURERS

1. Contact Office - Name/Address (and Manufacturing Site for Devices)
2. Phone Number
3. Report Source (Check all that apply): [ ] Foreign [ ] Study [ ] Literature [ ] Consumer [ ] Health Professional [ ] User Facility [ ] Company Representative [ ] Distributor [ ] Other:
4. Date Received by Manufacturer (mo/day/yr)
5. (A) NDA #: IND #: PLA #: Pre-1938: [ ] Yes OTC Product: [ ] Yes
6. If IND, Give Protocol #
7. Type of Report (Check all that apply): [ ] 5-day [ ] 15-day [ ] 10-day [ ] Periodic [ ] Initial [ ] Follow-up #
8. Adverse Event Term(s)
9. Manufacturer Report Number

H. DEVICE MANUFACTURER ONLY

1. Type of Reportable Event: [ ] Death [ ] Serious Injury [ ] Malfunction [ ] Other:
2. If Follow-up, What Type? [ ] Correction [ ] Additional Information [ ] Response to FDA Request [ ] Device Evaluation
3. Device Evaluated by Manufacturer? [ ] Not Returned to Manufacturer [ ] Yes [ ] Evaluation Summary Attached [ ] No (Attach page to explain why not) or provide code:
4. Device Manufacture Date (mo/yr)
5. Labeled for Single Use? [ ] Yes [ ] No
6. Evaluation Codes (Refer to coding manual): Method: - - - Results: - - - Conclusions: - - -
7. If Remedial Action Initiated, Check Type: [ ] Recall [ ] Repair [ ] Replace [ ] Relabeling [ ] Notification [ ] Inspection [ ] Patient Monitoring [ ] Modification/Adjustment [ ] Other:
8. Usage of Device: [ ] Initial Use of Device [ ] Reuse [ ] Unknown
9. If action reported to FDA under 21 USC 360(l), list correction/removal reporting number:
10. [ ] Additional Manufacturer Narrative and / or 11. [ ] Corrected Data

FORM FDA 3500A (9/03) (Back)

Complaint Record, BPV

BARD

04/21/2004
Page : 1

COMPLAINT RECORD DETAIL REPORT

Complaint : 5992

Complaint Entered By: Walcott, Cindi
Date Opened: 4/15/04 10:24 am
Complaint Status: Pending Investigation

Complainant Information :

Short Description:
RF-048F Migration
Country of Event : United States
Customer Contact Name: Redacted
Phone:
Customer Medical Facility / Organization:
Redacted

Business Unit: Interventional
Title/Dept: R.N., Risk Coordinator
Email:

Report Source: User Facility
Complainant Contact Name: Redacted
Health Professional: Yes
Phone: Redacted

Report Source - Other:
Occupation: R.N. Risk Coordinator
Email:

Complainant Medical Facility / Organization :

Sales Rep: BourBeau, Dave

Results Letter Requested?:

Acknowledgement Method: Letter
Contact Log:

4/14/04 C.Walcott spoke with Redacte at Redacted Risk and Compliance Dept. stated that the patient was not a bariatric patient. Dr Banner from Montcalm county was the medical examiner who performed the autopsy and reported the incident to the hospital. 989-584-3131, x 214. Hospital sent MDR to FDA on 4/14/04. Faxed copy to BPV on 4/14.
4/15/04 C. Walcott left voice mail at 10:30am for Dr. Banner at Carson City Hospital. Requested return phone call. Spoke with receptionist at office. She stated that the doctor did wish to speak with us. However, he was in a case and had several to follow. She stated that he would not be able to contact us until tomorrow. Left C. Walcott and Janet Hudnall's extension.
4/16/04 Dr. Banner left voice mail for C. Walcott at 6am
4/16/04 C.Walcott spoke to Dr. Banner at 8:30am. Dr. Banner stated that he would not allow anyone to touch the specimen (filter/clot). He stated this event is now involved in litigation. He had not performed histology on the clot, but stated by appearance it was an antemortem clot. He stated that any comments about where the clot formed (legs/vena cava/heart) would be supposition. He stated that the ventricle ruptured. Dr. Banner reported that the family informed him that the patient would be cremated today and reported that the pt's. son's name was Redact 1808-844-1012. A conference call was set up with Dr. Banner at 2pm EDT today.
4/16/04 Teleconference with Dr. Banner, D.Uelmen, J.Hudnall, R.Carr, C. Walcott: Dr. Banner stated that the current measured size of the clot was 2.5cm x 4.5cm. He stated that the clot shrank from the original estimated size of 3cm x 5cm due to the formalin fixative. He stated that the filter "prongs" had penetrated the right ventricle. The patient experienced cardiac tamponade and heart rupture. Dr. Banner estimated the cava size to be "33.5cm" in diameter at the time of autopsy. Dr. Banner stated he contacted the patient's family and told them Bard had contacted him and Bard "was handling the investigation in a forthright manner".
4/16/04 Teleconference with Redacted Interventional Radiologist, D.Uelmen, J.Hudnall, R. Carr, and C. Walcott. stated that the filter was initially placed 1-1.5 cm below the renal vessels. He stated it was an ideal placement and deployment. All legs deployed and filter was straight. He stated he DID NOT measure the vena cava size prior to placement. Filter indication: Pt. developed DVT's while in the hospital for treatment for a subarachnoid hemorrhage,

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COMPLAINT RECORD DETAIL REPORT

Complaint : 5992

which contraindicated the use of anticoagulants. Redact asked if this type of event had happened before, as other company's representatives have informed him that there were "numerous" events. D. Uelmen reviewed the Recovery Filter history with [redacted]
4/19/04 Dr. Banner met with Doug Uelmen, Rob Carr and Janet Hudnell at Carson City Hospital. Digital pictures were taken of the clot. Clot, after fixation measured 2.5cm x 4.5cm. Dr. Banner stated that there were small PE in the lungs, and the clot in the filter was ante-mortem. X-rays of the filter show that the filter was in tact, with all of the arms and legs, and hooks attached. Final autopsy report will be available the week of May 4.
4/19/04 Meeting with [redacted], Interventional Radiologist, Redacted is chairman of the department and was not the implanting physician. It was confirmed that the cava size was not measured predeployment, but [redacted] stated it was an appropriate size. There was a sizing catheter seen in the cava on reviewing the films. A post deployment cavagram was not taken. Therefore, it could not be determined if the legs were properly engaged. The Xrays were not released to Bard.

Product Information :

Product Catalog No: RF048F
Product Minor: 605
Product Major: 45
Product Segment: 42
Product Name: Recovery Filter

Type of Device: Vena Cava Filter

Trending Group:

Manufacturing Site: CR BARD, INC.
Manufacturing Lot No:
Corporate Lot No: 07LN2037
Serial No:
Expiration Date: 02/2007

Event Information :

Date of Event : [redacted]
Event Description :

Date of Awareness : 04/14/2004

It was reported that the patient had an IVC filter placed after developing DVT's prior to discharge from the hospital.The patient died at home 7 days after discharge from the hospital. The initial results of the post mortem reveals the IVC filter in the right ventricle, causing perforation. The medical examiner reported to the hospital that the patient had a fatal complication of the implantation. The filter caught a large burden of clot, dislodged the filter, and perforated the right ventricle.

US Reportability Category : M - MDR Reportable

Other FDA Report Number : 2300038-2004-0002
Other FDA Report Date : 04/14/2004

Location of Event : Home
Relevant Tests and Lab Data:

Europe Reportability Category :

Canadian Reportability Category : N/A
Other Vigilance Report Number :

Date of Death : Redacte

Operator of Device: Health Professional

Operator Name: Redacted
Implant Month:
Implant Day:
Implant Year:

Operator of Device-Other:

Operator Phone: Redacted
Explant Month:
Explant Day:
Explant Year:

Usage of Device: Initial

Type of Procedure: Vena Cava Filter insertion-Femoral

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Page : 1

COMPLAINT RECORD DETAIL REPORT

Complaint : 5992

FDA Device Code - FA: 1395 - Migration
Sub-Device Code - FA:

Patient Information :

Patient Name :
Age at Time of Event : 55
Weight : 80 Kgs
Other Relevant History :
Patient ID: [redacted]
Sex: F
Patient Code :

Admitted to the hospital on [redacted] for subarachnoid hemmorrhage.

Concomitant Therapy :

Sample Request :

Sample Available : Unknown
Investigation Required ? : Yes
Invest. Exemption Rationale :
X-Ray/Photo :

Quantity Affected : 1
First Date Sample Requested :
Quantity Expected to be Returned : 0
Non-destructive Testing Requested :

Sample Return No :
International Sample Return No :
International Sample Receipt Date :

Sample Recieved Information :

Date Sample Received from Customer :
Sample Disposition :
Quantity Returned :

Additional Information :

Service Record No :
Attachements:
5992.doc

Reference Complaint 1 :
3rd Party Report No :
Reference Complaint 2 :

Customer Accomodation Type : None
Customer Accomodation Details :

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Page : 1

COMPLAINT RECORD DETAIL REPORT

Complaint : 5992

Closure :

Complaint Summary :

Closed By : Closed Date :

Children Records :

Date Opened	Rec ID	Record Type	Assigned To	Status
04/15/2004	6070	MDR	Cindi Walcott	Opened
04/15/2004	5997	MDR Decision Tree	Cindi Walcott	Closed - Done
04/15/2004	6025	Investigation	Chris Dorvee	Opened

Emergency Services
Document Record

MONTCALM COUNTY EMERGENCY SERVICES DOCUMENTATION RECORD

☐ TRANSPORT
☐ NON-TRANSPORT

PATIENT NUMBER: [redacted] | DATE OF SERVICE: Redacted | UNIT 11 | INCIDENT #

Location of Incident: [redacted]	Nature of Call: MED 5 — P-5 DOA	Responding From: St 4
		Road Conditions: Dry

Patient Last Name	First Name	M.I.	Sex	Phone Number	Date of Birth	Age
[redacted]	[redacted]	[redacted]	♂	(616)	[redacted]	54

Patient Address (Street No. & Name)	City	State	Zip Code
[redacted]	[redacted]	MI	[redacted]

TIME INFORMATION

Dispatched	0939
En Route	0942
At Scene	1003
At Patient (est.)	1005
Depart Scene	
At Dest.	
Available	
End of Run	

Weight (Kg.)	Priority
80	5

MECHANISM OF INJURY
☒ Medical

CHIEF COMPLAINT: D.O.A

CLINICAL IMPRESSION: DOA

IMPACT TYPE: ☐ Frontal ☐ Frontal Angle ☐ Driver's Side ☐ Pass. Side ☐ Rear ☐ Rollover ☐ Unknown

MECHANISM: ☐ Fall <6' ☐ Fall 6-10' ☐ Fall >10' ☐ 0-15 MPH ☐ 16-30 MPH ☐ 31-60 MPH ☐ > 61 MPH

ASSESSMENT

TIME	BLOOD PRESSURE	PULSE RATE	PULSE QUAL	RESPIRATION RATE	RESPIRATION QUAL	BREATH SOUNDS L	BREATH SOUNDS R	SKIN	PUPILS	GCS E	GCS V	GCS M	EKG	SpO2	COMMENTS
1007	—	0	—	0	—	Abs	Abs	ccyD	D=N	1	1	1	Asystole		

MEDICATIONS

Vicodin, Phenytoin
Nimotop
☐ None

HISTORY

___ Asthma ___ CABG ___ Cancer ___ CHF ___ Diabetes
___ COPD ___ Hypertension ___ MI ___ Recent Surg ___ Renal Failure
___ Seizures ___ CVA/TIA ___ Subst. Abuse ___ Tobacco Use ___ Tuberculosis
Other: Subarachnoid Hemorrhage 2° to Ruptured Aneurysm

ALLERGIES

☒ NKDA

BLOOD GLUCOSE

TIME	READING
1007	EHBG

AIRWAY MANAGEMENT

TIME	PROCEDURE	SIZE	ATTEMPT/SUCCESS	BY
			/	
			/	
			/	
			/	
			/	
			/	

OXYGEN: TIME ___ FLOW ___ NC ☐ MASK ☐ BVM ☐

ET TUBE INFORMATION — SECURED BY: Tube Tie ☐ Holder ☐ DEPTH:

HOSPITAL CONFIRMATION

VASCULAR ACCESS

TIME	SITE	SIZE	ATTEMPT/SUCCESS	BY	RATE TOTAL VOLUME	DURATION
			/		/ ml	
			/		/ ml	
			/		/ ml	

Narrative: Hx) Apparently per Dr's office in GR was discharged from BDH on Redact c̄ SubArachnoid Hemorrage 2° to Ruptured Aneurysm pt's Medications reflect Dx. Pt Dispatched for check well being. Gained Access to find pt DOA in Bed. A) EAU. pt lying RLR in Bed. Covered c̄ Linen. AVOXO ⊖ LOC. HEENT/NCAPE c̄ NST pt c̄ Rigor/Liver mortis. Body Rigid in Position Found. Medication Count was Accurate for prescription dates. pt pronounced @ 1007 by Dr. Albrecht. GDPS Mark Thompkins #[illegible] on Scene c̄ approval for Removal. Body c̄ [illegible] shirt, [illegible] underwear, [illegible] buttons, socks. No Jewelry noted. Body [illegible] @ request [illegible] clothing left on [illegible] Body. Body Released to [illegible] Bill [illegible]

NEUROVASCULAR FUNCTION

TIME	Left Arm	Right Arm	Left Leg	Right Leg
1007	—	—	—	—

TRAUMA

Position: ☐ Sitting ☐ Laying ☐ Standing ☐ Driver ☐ Front Pass. ☐ Rear Pass. ☐ Restrained ☐ SRS

Indication: ☐ LOC ☐ Subst. Use ☐ N/S Deficit ☐ Spinal Pain ☐ Fracture ☐ Fx/spasm ☐ Shock

PERSONNEL

Driver		#
Attendant	M KASPEZ	# 407
Attendant	D CASE	# 821

DESTINATION

Facility: CCH Morgue
Physician Name: Bonner
Physician Signature:

Destination Determination: ☐ Nearest Appropriate ☐ Patient/Family Request ☒ Medical Control

PHARMACEUTICALS

IV Bag #	Med Bags
Log #	Red Tag #
Tape #	Yellow Tags

ES-400 (9/03) *White – Agency* *Canary – Receiving Facility* *Pink – Pharmacy*

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

BPV-17-01-00153599
LMD1

Certificate of Death,
Dr. James Banner

04/13/2004 11:09 6162438785 STEGENGAFUNERAL PAGE 03

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF DEATH

LF
CF

STATE FILE NUMBER 2390656

DECEDENT

1. Decedent's Name: [redacted]
2. Date of Birth: [redacted]
3. Sex: Female
4. Date of Death: [redacted]
5. Name at Birth or Other Name Used for Personal Business: [redacted]
6a. Age - Last Birthday (Years): 55
7a. Location of Death / Hospital or Other Institution: [redacted]
7b. City, Village, or Township of Death: [redacted]
7c. County of Death: Montcalm
8a. Current Residence - State: Michigan
8b. County: Montcalm
8c. Locality: [redacted]
8d. Street and Number: [redacted]
8e. Zip Code: [redacted]
9. Birthplace: [redacted]
10. Social Security Number: [redacted]
11. Decedent's Education: [redacted]
12. Race: [redacted]
13. Ancestry: [redacted]
13b. Hispanic Origin: No
14. Was Decedent Ever in the U.S. Armed Forces: No
15. Usual Occupation: [redacted]
16. Kind of Business or Industry: [redacted]
17. Marital Status: [redacted]
18. Name of Surviving Spouse: Redact

PARENTS

19. Father's Name: [redacted]
20. Mother's Name Before First Married: [redacted]

INFORMANT

21a. Informant's Name: [redacted]
21b. Relationship to Decedent: Son
21c. Mailing Address: [redacted]

DISPOSITION

22. Method of Disposition: Cremation
23a. Place of Disposition: Redacted
23b. Location: Redacted
24. Signature of Mortuary Science Licensee: Kurt B. Stegenga
25. License Number: 6723
26. Name and Address of Funeral Facility: Redacted

CERTIFICATION

27a. Certifier: [ ] Certifying Physician [X] Medical Examiner
Signature and Title
28a. Actual or Presumed Time of Death: Unknown
28b. Pronounced Dead On: Redacted
28c. Time Pronounced Dead: 10:07 A.M.
29. Medical Examiner Contacted? Yes
30. Place of Death: Home
27b. Date Signed: Redacted
27c. License Number: MI5101011192
32. Medical Examiner's Case Number: MEA04-085
33. Name of Attending Physician if Other Than Certifier:
34. Name and Address of Certifying Physician: James D. Bannan, D.O., 406 E. Elm Street, Carson City, MI 48811
35a. Registrar's Signature:
35b. Date Filed:

CAUSE OF DEATH

36. Part I.
a. Cardiac Rupture — Minutes
b. Puncture of Right Ventricle by Inferior Vena Cava Placed Filter — Days
c.
d.

Part II. Other significant conditions contributing to death but not resulting in the underlying cause given in Part I

37. Did Tobacco Use Contribute to Death: [ ] Yes [ ] Probably [X] No [ ] Unknown
38. If Female: [ ]
39. Manner of Death: Accidental
40a. Was an Autopsy Performed: Yes
40b. Were Autopsy Findings Available Prior to Completion of Cause of Death: Yes

MEDICAL EXAMINER

41a. Date of Injury: Unknown
41b. Time of Injury: Unknown
41c. Describe How Injury Occurred: Inferior Vena Cava Filter Placed for DVT's Dislodged by Thrombus and Migrated to Heart
41d. Injury at Work: No
41e. Place of Injury: Home
41f. If Transportation Injury:
41g. Location: [redacted] [redacted] MI

Patient Comparison Matrix

Complaint No.	Special Access Program Patient # 9	Special Access Program Patient # 46	6103139026	6103139086	3004720023	6104330050	6092
Account	Redacted						
Date of Event							
Date Event Reported to Bard	8/22/2000	3/26/2003	10/17/2003	12/1/2003	2/9/2004	2/24/2004	4/14/2004
Date MDR Submitted	Prior to 510(k)	Prior to 510(k)	11/14/2003	12/23/2003	3/9/2004	3/18/2004	Hospital 4/13/2004 Bard's due 5/13/2004
Lot No.	UNK	UNK	Unconfirmed-07DN3645 or 07DN3651	UNK	07GN3276	07JN2625	07LN2037, 37 units in lot
Sample returned	No	No	No	Yes	Yes	No	Unknown as of 4/2/2004
Filter Indication	UNK	Pre-Laparotomy / Hysterectomy	PE	Massive Retroperitoneal Bleed from anticoagulation. Anticoagulant had to be stopped.	Pre-Laparoscopic Gastric Bypass Surgery	DVT in legs	DVT
Other Pt. History	UNK	Large Uterine Fibroid	UNK	Left DVT, Multiple PE	Morbid Obesity, Obstructive Sleep Apnea, Atrial Fibrillation, DVT, Hypertension Cardiomegaly	Post spinal surgery.Decompression of cervical discs.	Sub arachnoid hemorrage
Pt. Age AT Time of Event	UNK	46	UNK	60	34	51	55
Sex	M	F	M	M	M	M	F
Wt.Lbs	UNK	UNK	UNK	UNK	500	UNK	80 kg
Normal Placement?	UNK	No. Legs twisted.	UNK	See "Cava Size" Change Below	Yes	No. Filter tilted 60 degrees. Legs twisted. Doctor unsuccessfully attempted to untwist them with a Cobra catheter.	Yes
Post Implant Symptoms	Asymptomatic	Asymptomatic	Chest Pains	SOB, Lightheaded	Patient "passed out" and coded after a Bili	Asymptomatic	None of record
Diagnostic Imaging	Frontal and lateral digital subtraction imaging	Abdominal X-ray, one day post implant	CT	CT	Vena-Gram	Vena-Gram	Pre Cava Gram, Post Film
Days to Movement Documented	16	1	13	13	6	Day of implant, during the procedure	13
Moved to?	T-11-T-12 disc space, one leg at level of renal vein	Cranial migration to T-12, one day post implant. "Filter tilted approx. 5 degrees to pt's. left, and approx. 10 degrees anteriorly".	4cm cephalad to above the Renals	IVC/Right Atrial Junction	Right Atrium	In right atrium on day of implant. During an attempt to retrieve it with a snare on day 1 post-implant, moved the filter to right ventricle.	Right ventricle, per Dr. Banner, filter "ruptured the ventricle"
Cava Size	UNK	UNK	UNK	12mm at implant (hypovolemic), 24mm after rapid fluid replacement	Verbally recorded to be "just below 24mm" by Dr. Powell	UNK	Appropriately sized per [redacted] 30-35mm at time of autopsy per Dr. Banner
Clot	"Large amount of thrombus within the filter"	"No thrombus seen in the filter".	"Large Clot in Filter post implant"	"Large amount of clot in the pulmonary arteries, right atrium, IVC, and possibly the renal veins" Large clot seen within the filter.	1" x 6" clot within the filter	Not reported	Per Dr. Banner's visual observation, clot was formed antemortem. No histology has been done on clot.
Patient Outcome	"Tolerated removal well, without developing any chest or abdominal pain"	"Successful removal of Recovery Filter. Successful placement of Tulip filter. The patient did not experience any acute complication".	OK	"Surgical Thrombo-embolectomy of the IVC, right atrium, bilateral pulmonary arteries. Post-op course unremarkable. No intraoperative complications. Procedure tolerated well."	Death	Unsuccessful attempt to retrieve the filter from the right atrium by another interventional Radiologist. Patient is scheduled for surgery week of [redacted]	Death [redacted] Reason for Death on Certificate: "Vena cava filter placed for DVT's dislodged by thrombus and migrated to heart."
Filter Removed	Filter removed per request of patient on day 16	Filter was removed, with difficulty, 1 day post implant. "Filter was not free floating". Tulip Filter placed through the same jugular access used for the Recovery filter removal. Tulip placed at L1-L2 interspace.	Still implanted as of [redacted]	Filter removed under CP bypass. Subsequently, a new filter was placed by a Radiologist w/o complications.	Filter removed at Autopsy	Scheduled for surgery week of [redacted]	Filter removed at Autopsy
Films	Not submitted to BPV	Not submitted to BPV	CT/Venogram @Dr. Kaufman	Not Released by Hospital	At BPV	Vena-grams at BPV 3/2	Digital images of films were taken by J. Hudnall

[redacted]

Investigation Summary,
Douglas Uelmen

BARD
PERIPHERAL VASCULAR

Investigation Summary
SPA 04-04-02
April 21, 2004

1. Patient Information.

- The patient was a 55 year old female weighing approximately 80kg.
- Admitted to [Redacted] in [Redacted] on [Redacte] for treatment of subarachnoid bleeding.
- Deep vein thrombosis (DVT) was discovered while at [Redacted]
- The patient was not a candidate for anti-coagulation therapy.
- A Recovery Filter (Catalog Number, RF048F, Lot Number 07LN2037) was placed on [Redacted]
- The Patient was released from [Redacted] on [Redacted]
- The patient was found by a Montcalm County EMT unit on [Redact] The patient was DOA in bed.

2. Post Mortem Information.

- A copy of the death certificate was provided by the Medical Examiner, Dr. Banner. The autopsy was performed by Dr. Banner at Carson City Hospital in Carson City, Michigan.
- "The cause of death is Cardiac Rupture." "A puncture to the right ventricle by an inferior vena cava placed filter" (see Death Certificate).
- The description of the occurrence is: "Inferior vena cava filter placed for DVT dislodged by thrombus and migrated to the heart" (see Death Certificate).
- During the meeting on 4/19/04 with Dr. Banner, he stated:
  - The size of the clot at the time of the autopsy was approximately 3 cm in diameter by 5 cm in length.
  - The size of the vena cava at the time of the autopsy was approximately 3.0 to 3.5 cm in diameter.
  - In his professional opinion, the clot was antemortem.
  - Small pulmonary emboli were found in the lungs. The PE was not measured.
  - The exterior surfaces of the filter were unremarkable (appeared normal). Interior surfaces were not evaluated.
- Digital photographs were taken of the specimen by a Bard group (J. Hudnall, R. Carr and D. Uelmen) on April 19, 2004. The specimen consists of the recovery vena cava filter with thrombus attached to a portion of the wall of the right ventricle.
- The Bard group with Dr. Banner measured the clot on April 19. The dimensions after the "fixing" was 2.5 cm in diameter by 4.5 cm in length.
- X-rays of the sample were taken to assess the status of the recovery filter embedded inside of the clot. Samples were taken from three planes.

- The x-rays show the filter to be intact. All "arms" and "legs" were attached. All hooks were present and properly formed.
- Dr. Banner indicated that the final autopsy report would be available during the week of May 4 (approximately 3 weeks after the completion of the autopsy.
- Dr. Banner provided the contact information for the county clerk. We will obtain a copy when it becomes available.
- The sample will be available for further pathological evaluation at the discretion of the deceased's family.

3. Information from the Interventional Radiologist. Although Redacte placed the filter, he was unavailable during our visit to Redacted on April 19. We discussed the case with the Chief of the Interventional Radiology Department, Dr. Redacted had the vena cava grams and films available for our review.

   - Although a formal measurement of the vena cava was not taken at the time of deployment a measuring catheter was seen in the vena cava. The marker bands of the catheter were at 2 cm increments. The physician determined the vena cava to be appropriately sized. There were no copies of the films available. Digital photographs were taken of the films on the light box.
   - The post deployment films show the filter to be placed as intended. A post deployment vena cava gram was not performed.
   - All of the "arms' and "legs" deployed properly. The lack of a post deployment vena cava gram made it difficult to determine if the legs were properly engaged.

4. The Division PAT reviewed the Recovery Vena Cava Filter MDR data vs. MDR data for competitive Vena Cava Filters. The Recovery Filter was compared to the Simon Nitinol Filter (Bard), the Vena Tech Filter (Braun), the Greenfield Filter (Boston Scientific), the Birds Nest Filter (Cook), the Gunther Tulip (Cook), the TrapEase Filter (Cordis), the OptEase Filter (Cordis). MDR information was obtained from the Maude data base. Sales information for competitors products was obtained from IMS data. Comparisons were made for the following categories:

   - Fatality Rate as a percentage of units sold.
   - Complication Rate (MDR) as a percentage of units sold.
   - Migration Rate as a percentage of units sold.
   - Fatal Migration Rate as a percentage of units sold.
   - Fatal migration as a percentage of total migration.

5. The Division PAT has completed the following activities in support of this investigation:

- The definition of Massive Thrombus is thrombus of sufficient size to cause the internal diameter of the inferior vena cava to distend beyond the maximum size indicated for the vena cava filter in the Instruction for Use.

6. The Division PAT was challenged to determine whether or not a filter without a recoverable indication could have resisted migration under the clot burden identified in this investigation.

   - A review of the Maude Data Base shows that all Vena Cava Filters (with the exception of the SNF) are subject to migration and are associated with deaths due to thromboemboli. Fatal migrations are found with; Birds Nest, Recovery Filter, Vena Tech and TrapEase.
   - A report retrieved from the Maude database concerning a Cordis TrapEase filter properly placed in 2003 is very similar to this incident. Post procedure the patient experienced shortness of breath, respiratory distress, and went into cardiac arrest however was resuscitated but did not survive. A post mortem was completed and it showed that the filter had migrated between the right atrium and right ventricle. The cause of the migration was reported to be a large embolic load with resulting increase in venous pressure that lead to inferior vena cava dilatation (greater that 30 mm) resulting in a release of the filter hooks and subsequent migration.

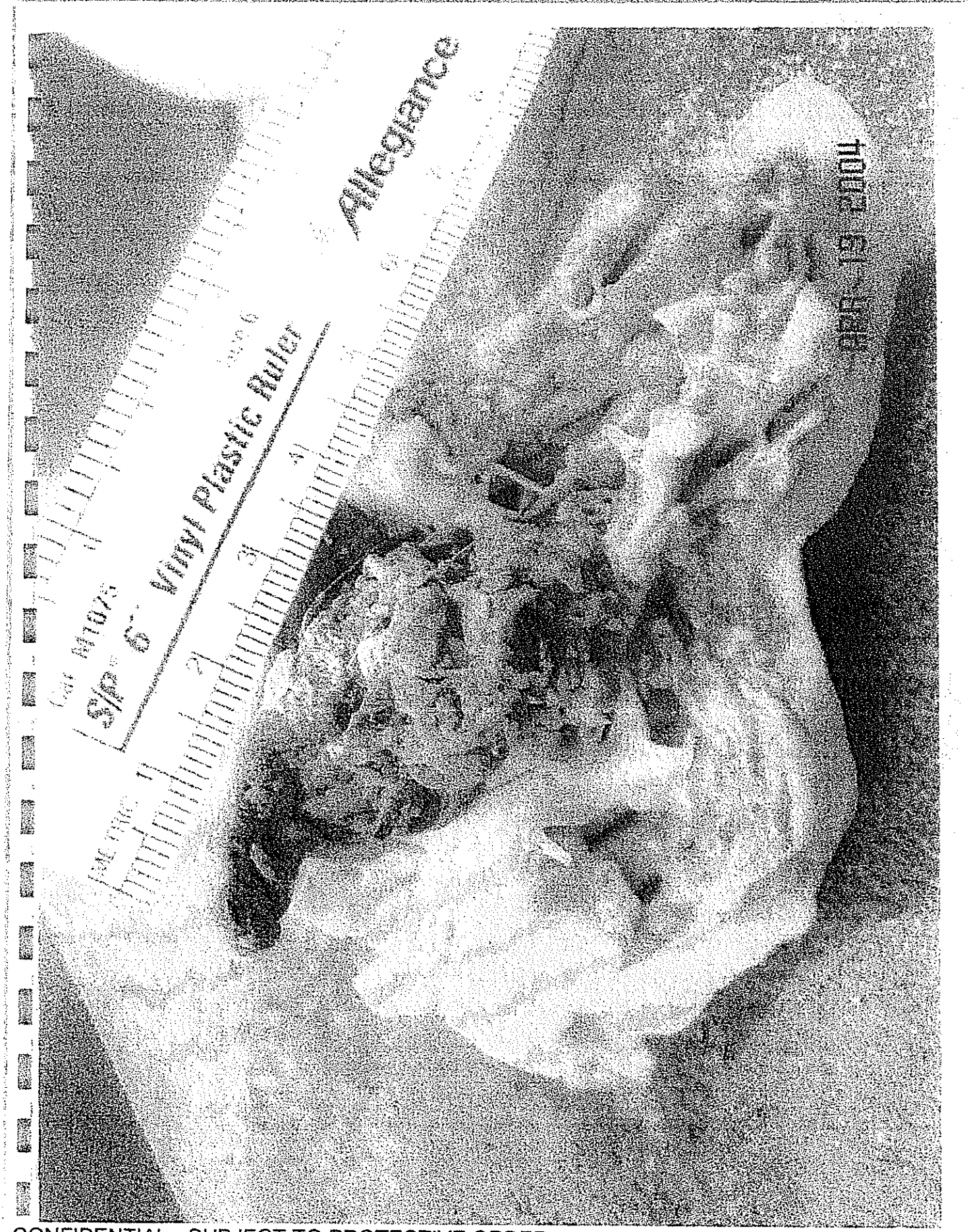
     This TrapEase filter is indicated for permanent use only. The conditions surrounding this migration are nearly identical to the issue under investigation. The Division PAT believes that based on this information that a clot of the size under investigation would have resulted in a condition similar to that stated in the above mentioned TrapEase investigation (reference MDR Text Key:1747578) resulting in migration and death.

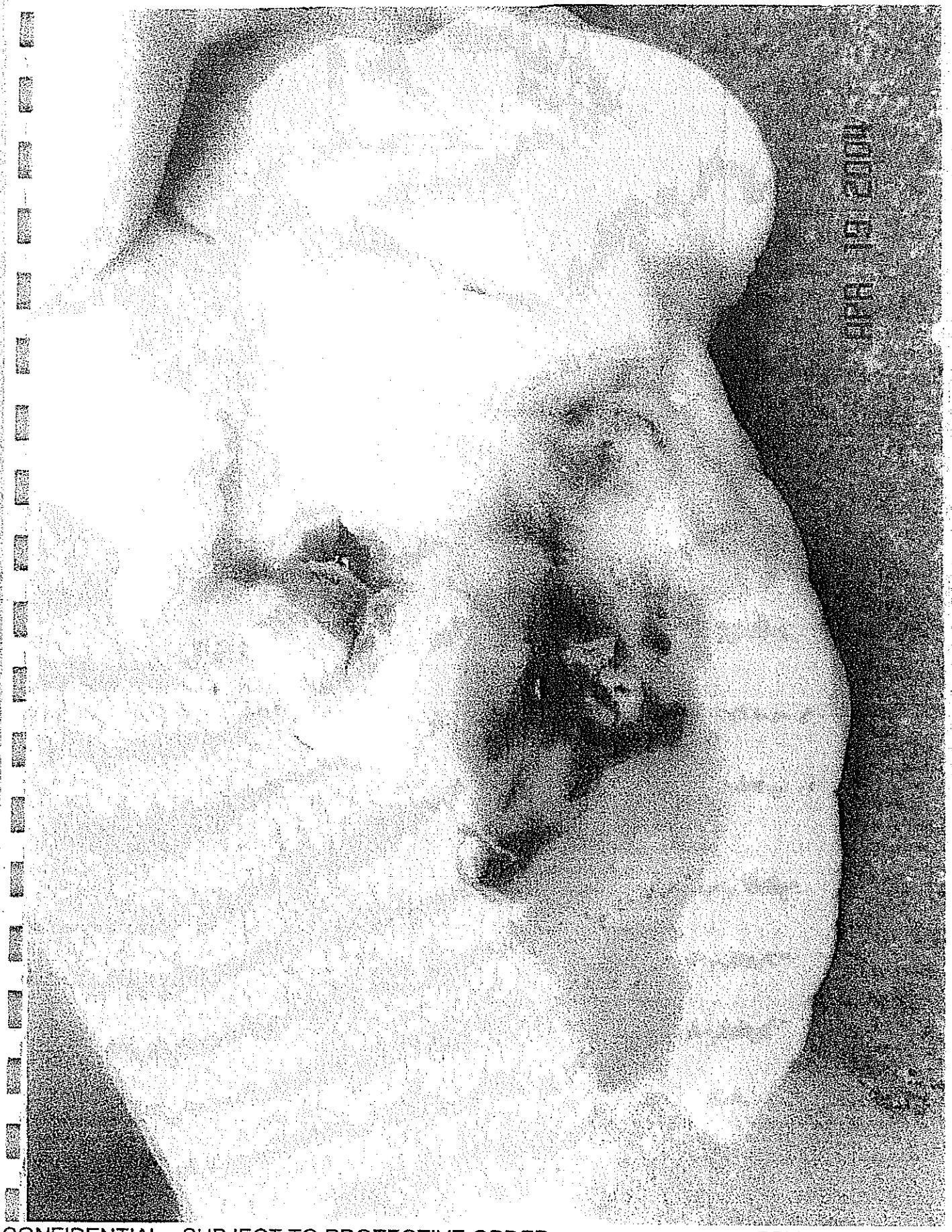
Photographs,
Cason City, MI 4/19/2004


APR 19 2004


APR 19 2007

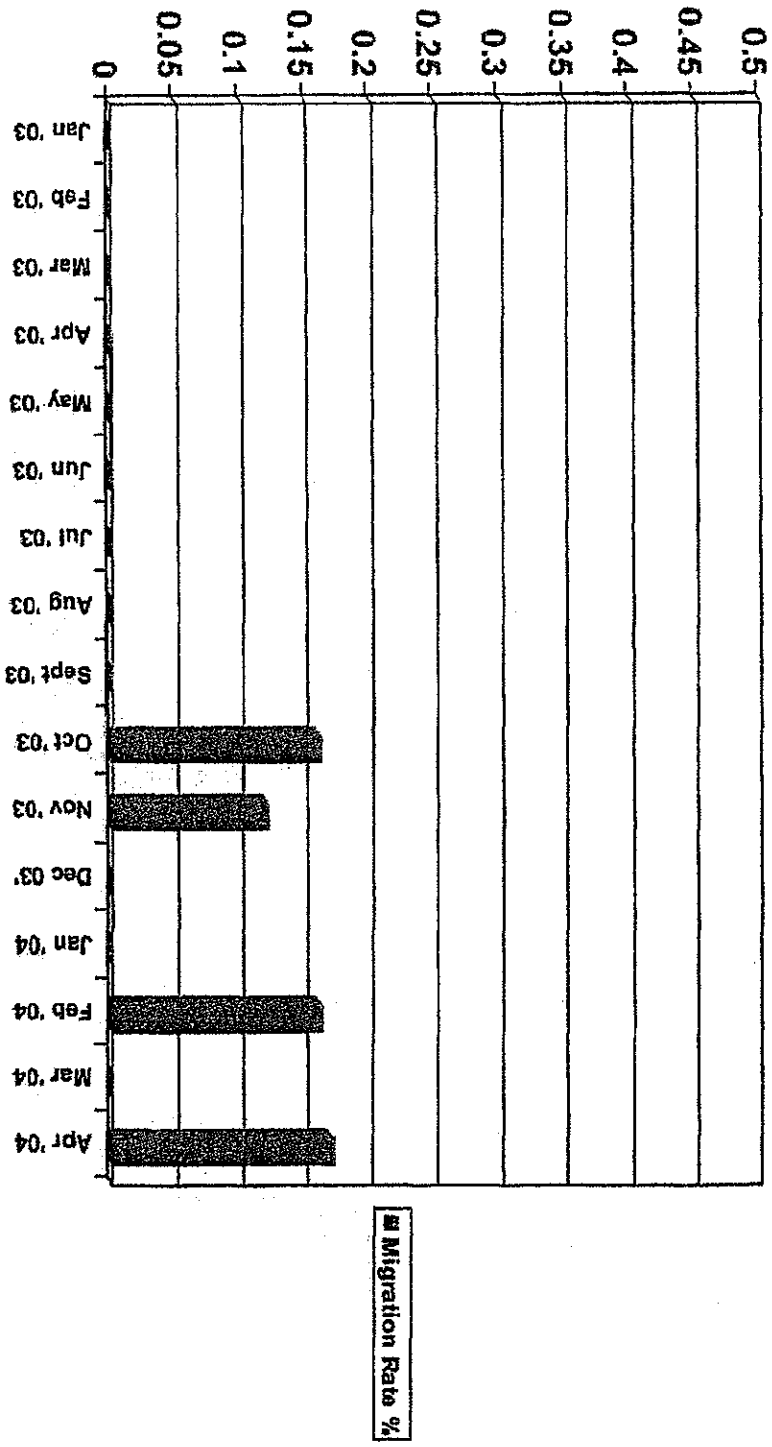

APR 19 2004


Allegiance
6" Vinyl Plastic Ruler
Made in China



Recovery Filter Migration
History Graph

Recovery Filter Migration Rate as a % of units sold



MAUDE Database
Summary & Graphs

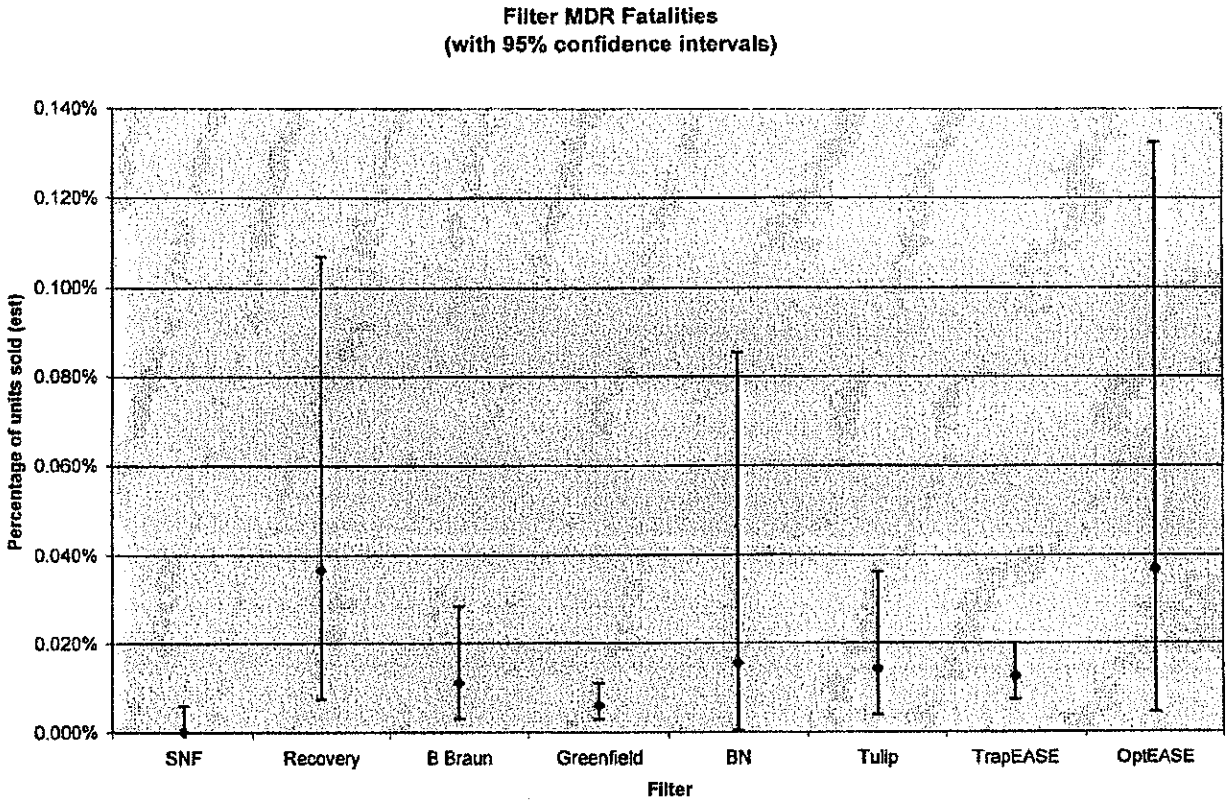
FILTER SALES

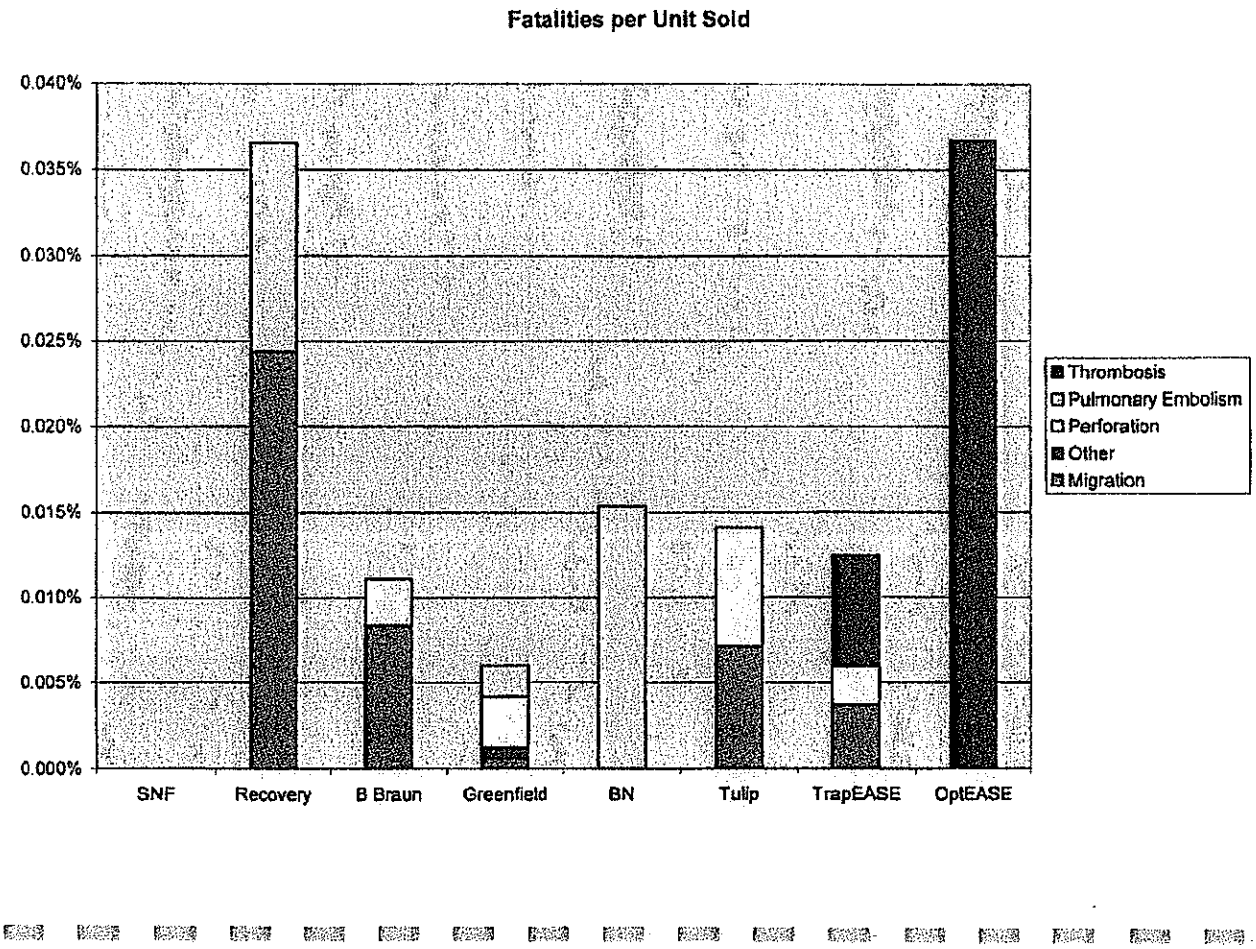
SNF	62346	Actual (01/00 to 04/04)
Recovery	8202	Actual (01/00 to 04/04)
Vena Tech	36031	IMS+ LR (01/00-Q1/04)#
Greenfield	167702	IMS+ LR (01/00-Q1/04)#
Bird's Nest	6517	IMS+ LR (01/00-Q1/04)#
Tulip	28348	IMS+ LR (01/00-Q1/04)#
TrapEase	136315	IMS+ LR (01/00-Q1/04)#
OptEase	5448	IMS+ LR (01/00-Q1/04)#

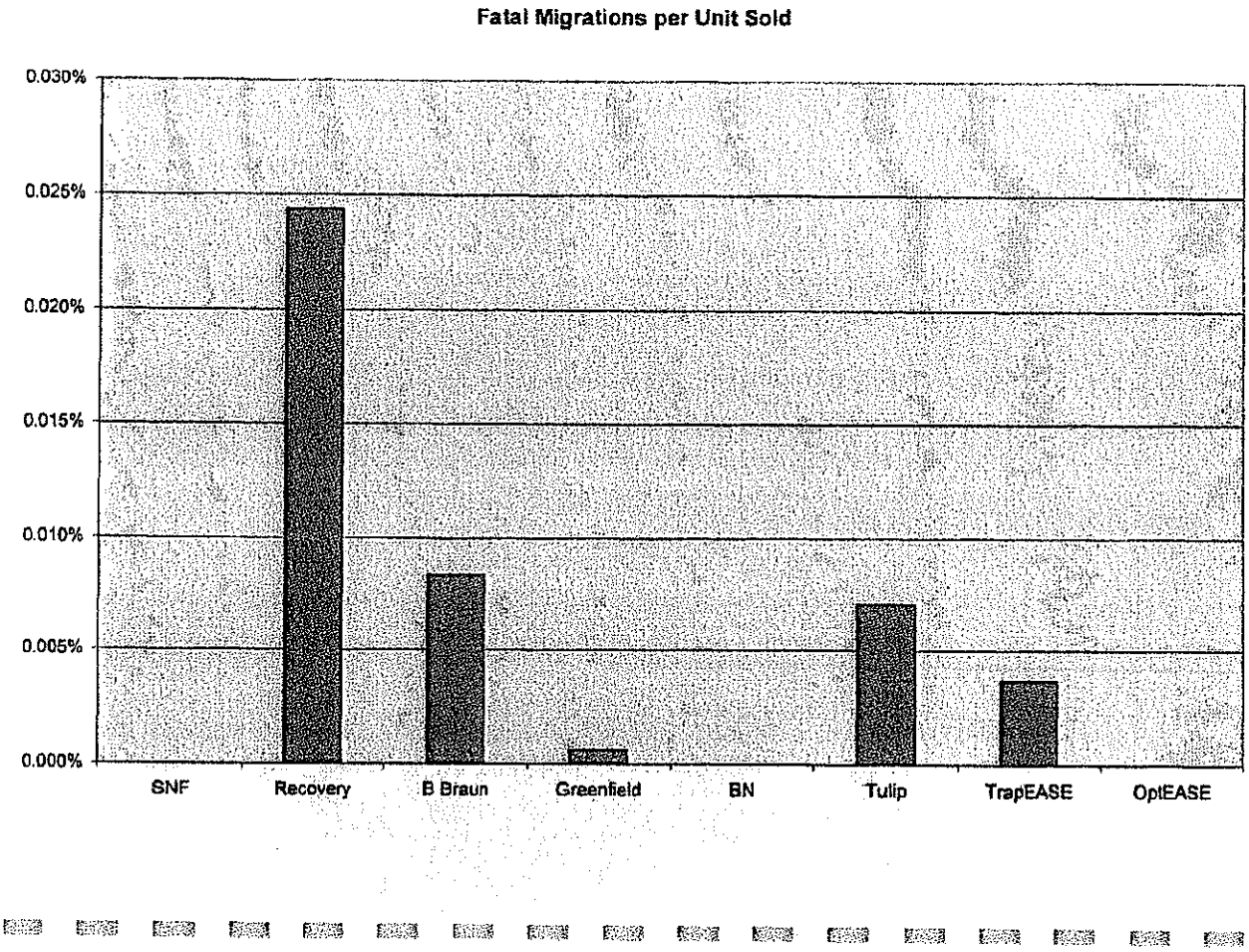
*MAUDE DATA AS OF Q1 2004**

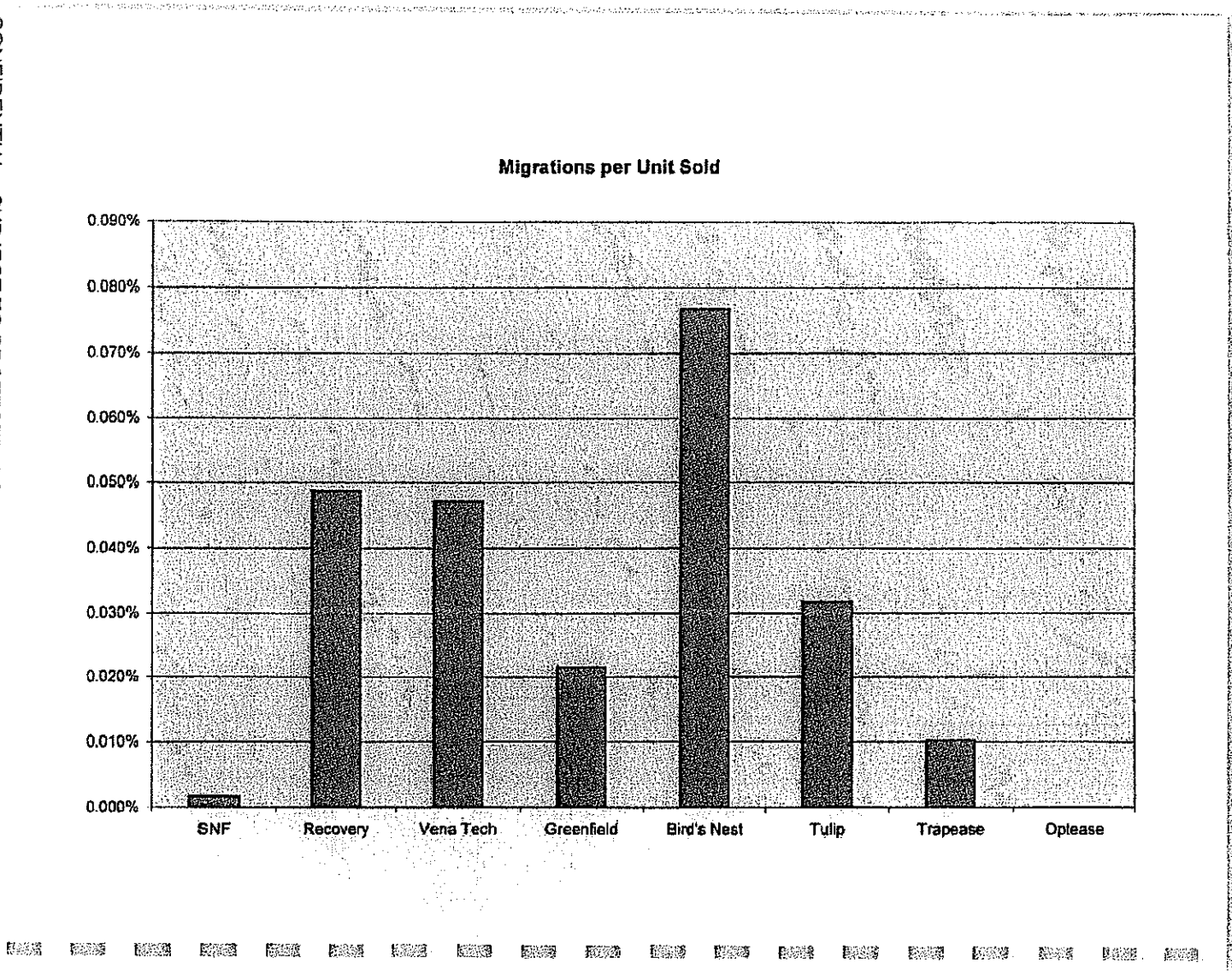
	Fatalities	Migration	Caval Perforation	Caval Thrombosis
SNF	0	1	5	0
Recovery	3	4	0	0
Vena Tech	4	17	0	0
Greenfield	10	36	7	0
Bird's Nest	1	5	7	0
Tulip	4	9	4	0
Trapease	17	14	11	51
Optease	2	0	0	1

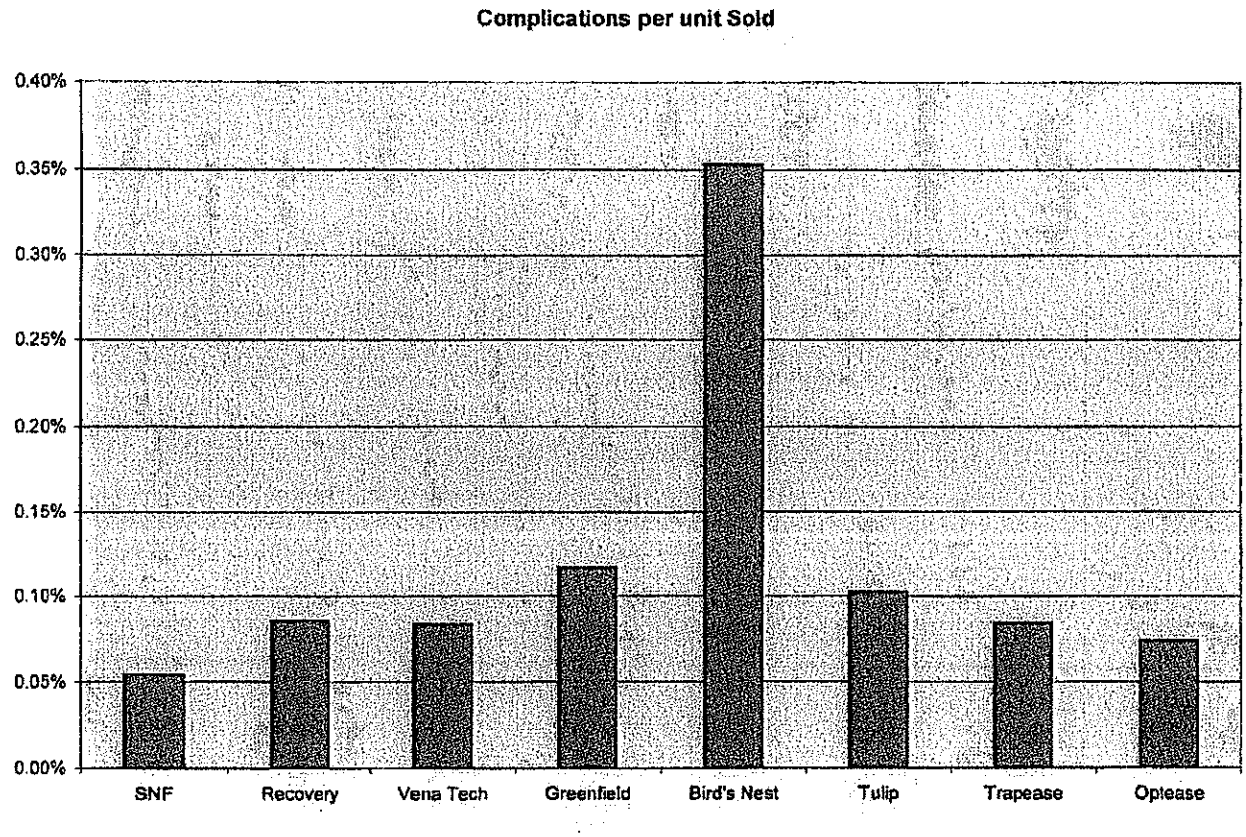
	Fatalities	Migration	Caval Perforation	Caval Thrombosis
SNF		0.002%	0.008%	
Recovery	0.037%	0.049%		
Vena Tech	0.011%	0.047%		
Greenfield	0.006%	0.021%	0.004%	
Bird's Nest	0.015%	0.077%	0.107%	
Tulip	0.014%	0.032%	0.014%	
Trapease	0.012%	0.010%	0.008%	0.037%
Optease	0.037%			0.016%

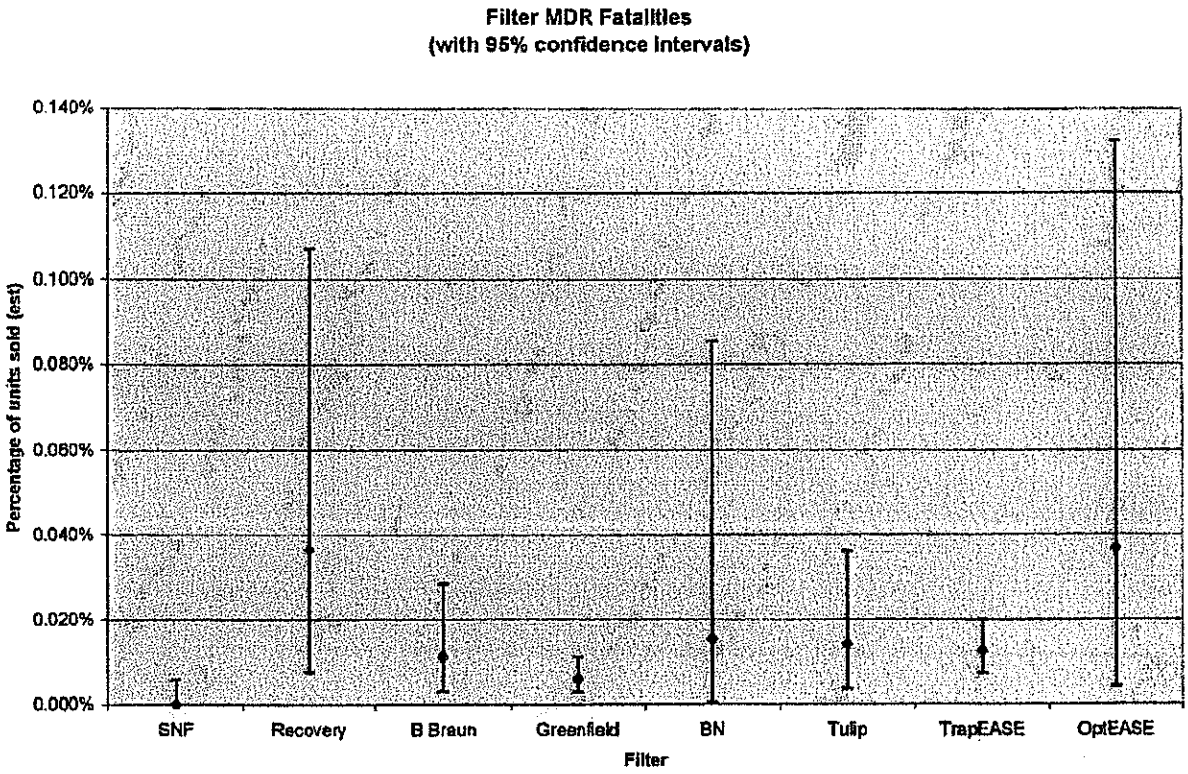












Confidence intervals of proportions

Num	3
Den	8202

	LCB	Proportion	UCB
"Exact"	0.007544%	0.036576%	0.106854%
Wilson	0.012440%	0.036576%	0.107492%

Removal of QC Hold,
Chris Ganser

Uelmen, Doug

From: Ganser, Christopher
Sent: Saturday, April 24, 2004 12:58 PM
To: Uelmen, Doug
Cc: Barry, Brian; Cherry, Joe; Passero, Donna; Palermo, Pete; Ganser, Christopher
Subject: Health Hazard Evaluation (HHE)- Rceovery Filter

Per phone discussion with Dr. John Lehmann MD today at 11:30 am, the HHE for the remedial action plan involving the Recovery Filter second patient death will not differ from the HHE provided with the first Recovery Filter remedial action plan involving a patient death. Dr. Lehmann stated that in his reveiw of the data involving IVC filter related deaths, the evidence to date does not suggest that these types of events are occuring with excess frequency with the Bard Recovery IVC. A formal HHE will be provided and the remedial action plan must be completed per the requiremnts of Corp. RA Policy R-002

With this information provided directly to me, I authorize you to remove the current internal QC HOLD for the Bard Recovery Nitinol Filter.

Christopher Ganser
Vice President, Regulatory Sciences

Health Hazard Evaluation,
Dr. John Lehmann

Lehmann Thomas, LLC

Memo

To: Doug Uelmen, BPV

From: John Lehmann, MD

Cc: Brian Barry, Corporate
Paul Kowalczyk, Corporate
Chris Ganser, Corporate

Date: April 27, 2004

Re: Recovery Filter Migration HHE

Doug, here's the completed Health Hazard Evaluation.

Regards, John W Lehmann MD

Summary of Health Hazard Evaluation: A case of vena cava filter migration associated with patient death was reported after the successful implantation of a Bard Recovery® Nitinol Vena Cava Filter. Evaluation demonstrated an intact filter and a large thromboembolus, with clot and filter lodging in the right ventricle resulting in cardiac perforation and tamponade.

Conclusion: Vena cava filter migrations are a recognized and accepted complication of this type of therapy. Such complications may be serious and can occasionally be fatal. The evidence to date does not demonstrate that these types of events are occurring with excess frequency with the Bard Recovery® Nitinol Vena Cava Filter.

Description of the problem: A complaint in April, 2004 regarding a Bard Recovery® Nitinol Vena Cava Filter (Recovery VC Filter) migration associated with a patient death led to a review of the potential health hazard associated with such occurrences.

Actual occurrence of injuries: The complaint involved a 55 year old female patient admitted to the hospital in [redacted] with subarrachnoid hemorrhage, who was found to have DVT during her hospitalization. Because of her recent intracranial hemorrhage, she was not a candidate for anticoagulation, and a Recovery VC Filter was placed on [redacted] in an approximately 25 mm diameter vena cava. The Recovery VC Filter was deployed approximately 1 cm below the lower renal vein, with normal placement found on post procedural vena cavagrams. The patient was discharged from the hospital on [redacted] to home; and was found dead in bed on [redacted]

Post mortem examination determined that the cause of death was cardiac rupture, with puncture of the right ventricle by inferior vena cava filter. The death certificate is said to describe an "inferior vena cava filter placed for DVT's dislodged by thrombus and migrated to the heart."

Inspection of the thrombus / filter mass on 4/19/04 revealed dimensions of 2.5 cm in diameter and 4.5 cm in length (which was slightly smaller than the dimensions noted immediately post mortem). The thrombus / filter mass was attached to the right ventricular wall. X-rays confirmed that all filter arms, legs and hooks were present, even though some of the hooks and legs were contained within the thrombus. The thrombus was determined to be ante mortem. The vena cava was estimated to have an internal diameter of 30 – 35 mm, but was otherwise unremarkable. Small pulmonary emboli were found in the lungs.

Human exposure to the problem: Embolism of vena cava filters is a generic and well recognized risk of this technology. Events have been reported in the medical literature since the early 1980s as well as in the MAUDE database; these reports include migrations to the heart and include fatal outcomes.

Male and female patients at risk of pulmonary embolism who are either unable to take anticoagulants, are anticoagulant failures, or who are at unusually high risk are generally indicated for the use of vena cava filters in general and the Recovery VC Filter in specific.

General consequences: Migration of vena cava filters can have minimal consequences in some patients. In others it results in damage to the vena cava or obstruction of the renal veins. If the device and associated thrombus migrates into the heart this can lead to direct impairment of cardiac function including valvular dysfunction, reduced cardiac output, perforation with tamponade, circulatory collapse and death.

Other recognized causes of mortality associated with vena cava filters are vena caval obstruction, vena caval perforation with damage to adjacent structures, and filter failure resulting in release of thrombus leading to pulmonary embolism.

Population exposed to risk: Generally adult patients with a high risk for pulmonary embolic disease.

Mitigating/predisposing factors in population at risk: Mitigating factors include the close medical attention such patients generally receive. Predisposing factors in this population include coagulation abnormalities, obesity, sleep apnea syndrome, perioperative condition, congestive heart failure, cardiac arrhythmia, prolonged immobility and anticoagulant intolerance / failure.

Nature and seriousness of the risk: The nature of the risk ranges from minimal (asymptomatic migration without sequelae) to catastrophic (acute circulatory impairment from pulmonary or cardiac embolization with clot, filter or both). The latter risk is serious and potentially fatal.

Likelihood of occurrence of problem: Considering the problem to be vena cava filter migration into or near to the heart, there have been 4 such migrations of the Recovery VC Filter, with two fatalities, in an estimated 8,200 sales through mid-April, 2004, for a rate of 0.05%. One instance was a deployment error, and the other three occurred after apparently normal deployments on Days 6, 13 and 14.

Considering the problem to be death in association with vena cava filter use (resulting from one of the four major known complications: migration, caval obstruction, caval perforation and pulmonary embolus / acute respiratory distress), there have been 3 deaths associated with the Recovery VC Filter, 2 from filter migration related to large thromboembolic load and one from a pulmonary embolus, for a rate of 0.037%.

These types of adverse events occur with all known types of vena cava filters, and are extensively reported in the medical literature. Comparative attempts to assess similar events via the MAUDE database do not yield reliable quantitative estimates for a number of reasons:

- Potential under-reporting
- Inadequate description of events in the MAUDE database, resulting in potential misclassification
- Very low frequency of observed events
- Sales data can only be roughly estimated
- High variability in event rates across devices and across time periods

However, it is clear that since the MAUDE database has been kept, numerous instances of vena cava filters migrating to the heart with both fatal and nonfatal outcomes have been reported, as well as fatalities from the other known complications associated with the implantation of such devices.

Likelihood of harm if problem occurs: The likelihood of harm if the Recovery VC Filter migrates to or near the heart is significant, but unquantifiable.

Is product essential to health?: Yes, vena cava filters are essential to health for the indicated patients, who may have no other alternative to prevent pulmonary embolism.

Is an alternative available?: Partially. Other manufacturers currently sell approved vena cava filters without a claim of recoverability, and there are also other medical and surgical options for some of these patients. However, there is only one other vena cava filter on the market with a claim of recoverability; this device has a similarly short marketing history to that of Recovery, no published clinical data, and an animal study that suggests incorporation of the struts into the caval wall after several weeks. Thus, the Recovery VC Filter may have unique advantages for certain patients.

Must the problem be corrected surgically?: Migration of vena cava filters to the heart is rarely managed conservatively, and treatment almost always requires either a percutaneous or open surgical correction.

Is the problem expected and within an acceptable statistical range?: Migration of vena cava filters, both within the vena cava and up to and into the heart are recognized complications of these devices. Acceptable statistical ranges cannot be reliably computed from available data, especially since many migrations without serious sequelae are not reported. Death associated with vena cava filter use, while a cruder measure, is probably subject to less under-reporting. Consideration of various estimates using this outcome measure do not demonstrate that these types of events are occurring with excess frequency with the Bard Recovery® Nitinol Vena Cava Filter. Such estimates are difficult to make reliably given the multiple data deficiencies noted above, and continued monitoring of event rates is warranted as further experience with the device is gained.

Can the problem be field corrected? In most of the serious or fatal complications involving vena cava filters (migration, caval perforation, caval occlusion and filter failure

with PE and / or acute respiratory failure) the device appears to be functioning normally up to the time of failure. Migration and filter failure generally occur when an otherwise normal filter is overwhelmed by aggregated large thrombus burdens. There is no device problem to be field corrected in this instance, just a recognized complication of vena cava filters.

Is it obvious to the user?: Migration of vena cava filters can be asymptomatic, but when they migrate to the heart this is clinically evident.

Can the product continue to be used with proper warnings?: Yes, the product can continue to be used with current warnings, which indicate the possibility of filter migration.

Is the device used only by specially trained health care professionals?: Yes, the device is only used by interventional radiologists and occasionally by other equally skilled interventionalists.

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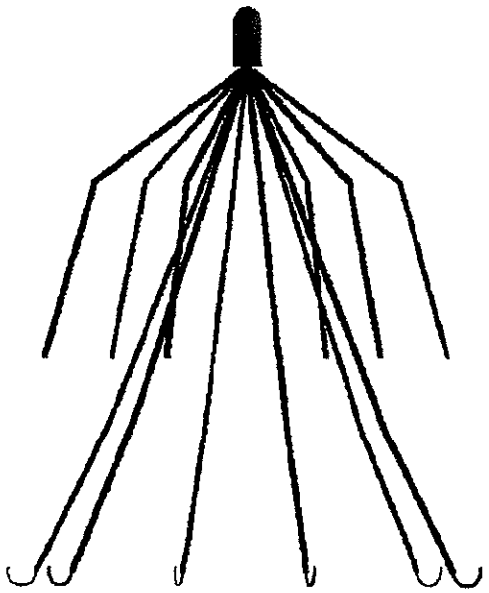
Draft of IFU Changes,
Mary Edwards

Recovery®
Filter System
for use in the Vena Cava

Instructions for Use



CE 0086

PK5014853 Rev. 00

A. General Information

Recovery® Filter System

Expiration Date.

Lot Number.

Attention, See Instructions for Use.

Sterilized by Ethylene Oxide.

Nonpyrogenic.

Single Use.
Do Not Reuse.

Do Not Resterilize.

Sterile, non-pyrogenic unless package is damaged or opened.

MRI compatible: MRI-safe and neither interferes with nor is affected by the operations of an MRI device.

Warning: After use, the *Recovery*® Filter System may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

Contents:
REF: RF-048F
Kit A: One (1) 7 Fr. Introducer Catheter 48 cm Long with Dilator
Kit B: One (1) *Recovery*® Filter Femoral Delivery System

Bard, Recovery, and Recovery Cone are registered trademarks of C. R. Bard, Inc. or an affiliate.

U.S. Patent No. 6,007,558 and 6,258,026.
Other U.S. and Foreign Patents Pending.

The *Recovery*® Filter represents a new generation of venous interruption devices designed to prevent pulmonary embolism. The unique design and material of the *Recovery* Filter provide excellent filtering efficiency and allow percutaneous placement through a standard 7 French I.D. angiographic introducer sheath with minimum entry site difficulties. The placement procedure is quick and simple to perform.

The Femoral set is designed to advance through its 48 cm, 7 French I.D. introducer catheter using a flexible, nitinol pusher wire. A pad at the end of the wire is designed to push on the filter apex and a grooved segment is designed to hold and properly orient the filter legs. These components secure the filter to the pusher wire as it advances the filter, tip first, to the distal end of the catheter, positioned below the lowest renal vein. When the tip of the filter approaches the tip of the introducer catheter, it will be positioned between the radiopaque markers on the introducer catheter. The introducer catheter and delivery assembly are then pulled back onto the pusher wire handle to unsheath and release the filter and allow it to recover to its predetermined shape. The centering system allows the *Recovery* Filter to be deployed with the filter tip centered and prevents the legs from crossing.

The *Recovery* Filter is designed to act as a permanent filter. When clinically indicated, the *Recovery* Filter may be percutaneously removed after implantation according to the instructions provided under the Optional Removal Procedure. The *Recovery* Filter's elastic hooks allow the filter to remain rigid and resist migration, but elastically deform when the filter is percutaneously removed. (See Optional Removal Procedure for specific removal instructions).

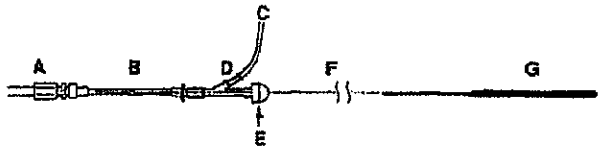
MRI Compatible: The *Recovery* Filter Implant is MRI-safe and neither interferes with nor is affected by the operations of a MRI device.

B. Device Description

The *Recovery* Filter System consists of the Filter and Delivery System. The *Recovery* Filter consists of twelve, shape memory nitinol wires emanating from a central nitinol sleeve. These twelve wires form two levels of filtration of emboli: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The *Recovery* Filter is intended to be used in vena cava with diameters up to 28 mm.

The *Recovery* Filter Delivery System is illustrated in Figure A. The Delivery System consists of a 7 French I.D. introducer sheath and dilator, the *Recovery* filter, a storage tube with saline infusion port, and a pusher system. The *Recovery* Filter is packaged pre-loaded within the delivery storage tube.

Figure A. Recovery® Filter System



A. INTRODUCER CATHETER
B. FILTER STORAGE TUBE
C. SALINE DRIP INFUSION SET
D. SIDE PORT
E. ADJUSTABLE TOUHY-BORST ADAPTER
F. NITINOL PUSHER WIRE
G. PUSHER WIRE HANDLE

IMPORTANT: Read instructions carefully before using the Recovery™ Filter

C. Indications for Use

The *Recovery* Filter System is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.

- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated. [redacted]

- Recovery filter may be removed according to the instructions supplied below under Section labeled: **Optional Procedure for Filter Removal.**

D. Contraindications for Use

CAUTION: If the corrected, inferior vena cava (IVC) diameter exceeds 28 mm the filter **must not be** inserted into the IVC.

The *Recovery* Filter should not be implanted in:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with vena cava diameters greater than 28 mm.
- Patients with risk of septic embolism.

E. Warnings

***Recovery* Filter Implantation**

1. The *Recovery* Filter vena cava filter is pre-loaded into the storage tube and is intended for single use only. Do not deploy the filter prior to proper positioning in the inferior vena cava (IVC), as the *Recovery* Filter cannot be safely reloaded into the storage tube.
2. Delivery of the *Recovery* Filter through the introducer sheath is advance-only. Retraction of the pusher wire during delivery could result in dislodgment of the Filter, crossing of Filter legs or arms, and could prevent the Filter from further advancement within the sheath.
3. The *Recovery* Filter System is designed for femoral approaches only. Never use the *Recovery* Filter and Delivery System for superior approaches (jugular, subclavian or antecubital vein), as this will result in improper *Recovery* Filter orientation within the inferior vena cava.
4. If large thrombus is demonstrated at the initial delivery site, do not attempt to deliver the filter through it. Attempt filter delivery through an alternate site. A small thrombus may be bypassed by the guidewire and introducer.
5. Only use the *Recovery* Cone® Removal System to remove the *Recovery* Filter. Never re-deploy a removed filter.
6. Never advance the guidewire or introducer sheath/dilator or deploy the filter without fluoroscopic guidance.

***Recovery* Filter Removal**

1. Do not attempt to remove the Recovery Filter if significant amounts of thrombus are trapped within the Filter or if the Filter tip is embedded within the vena caval wall.
2. Use only the Bard *Recovery* Cone® (packaged separately) to retrieve the *Recovery* Filter. Use of other devices has resulted in recurrent pulmonary embolism.

F. Precautions

***Recovery* Filter Implantation**

1. The filter should be placed in the suprarenal position in pregnant women and in women of childbearing age.[1]
2. Anatomical variances may complicate filter insertion and deployment. Careful attention to these instructions for Use can shorten insertion time and reduce the likelihood of difficulties.

[redacted]

[1] ACR Standard For The Performance Of Percutaneous Permanent Inferior Vena Cava (IVC) Filter Placement For The Prevention Of Pulmonary Embolism - 2000 (Res.12), Effective 01/01/01

6. *Spinal deformations*: It is important to exercise care when contemplating implantation in patients with significant kyphoscoliotic spinal deformations because the inferior vena cava may follow the general course of such anatomic deformations. This may make percutaneous removal of the filter more difficult.

***Recovery* Filter Removal**

1. Anatomical variances may complicate insertion and deployment of the *Recovery Cone*® Removal System. Careful attention to these Instructions for Use can shorten insertion time and reduce the likelihood of difficulties.
2. *Spinal deformations*: It is important to exercise care when contemplating removing the *Recovery* Filter with the *Recovery Cone* Removal System in patients with significant kyphoscoliotic spinal deformations because the inferior vena cava may follow the general course of such anatomic deformations. This may require advanced techniques to remove the filter.

G. Potential Complications

[redacted]

[redacted] *Migration of the filter.* This may be caused by placement in oversized vena cava diameters exceeding 28 mm or if proper anchoring techniques are not utilized. [redacted]

- *Perforation* [redacted] *of the vena cava wall.* This may occur if proper insertion technique is not utilized.
- *Acute or Recurrent pulmonary embolism.* This has been reported despite filter usage. It is not known if thrombus passed through the filter or via collateral means.
- *Caval* [redacted] *(occlusion).*

[redacted]

H. Equipment Required

The following equipment is required for use:

- One *Recovery* Filter and Delivery System that contains:
  - One 48 cm, 7 French I.D. introducer sheath and dilator set
  - One storage tube with pre-loaded *Recovery* Filter and pusher delivery system
- 0.038" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Sterile extension tube for saline drip or infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

- An entry kit consisting of a 0.038" 3 mm J-tipped guidewire, entry needle, #11 scalpel and 10-cc syringe is available from C. R. Bard, Inc., catalog number 4000E.

If the physician chooses to percutaneously remove the *Recovery*® Filter, the *Recovery Cone*® Removal System is available from C. R. Bard, Inc.

I. Instructions for Use

Insertion of the 7 French Introducer Catheter and Preliminary Venography

1. Select a suitable femoral venous access route, on either the right or left side, depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the filter package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18 gauge entry needle.
5. Insert the J-tipped guidewire and gently advance it into the distal vena cava or iliac vein.

   NOTE: If resistance is encountered during a femoral insertion procedure, withdraw the guidewire and check vein patency fluoroscopically with a small injection of contrast medium. If a large thrombus is demonstrated, remove the venipuncture needle and try the vein on the opposite side. A small thrombus may be bypassed by the guidewire and introducer.
6. Remove the venipuncture needle over the J-tipped guidewire. Advance the 7 French introducer catheter together with its tapered dilator over the guidewire and into the distal vena cava or the iliac vein.

   NOTE: The introducer catheter has radiopaque markers to assist in visualization and predeployment filter positioning. The radiopaque markers on the introducer catheter provide a "target" location between which the filter should be positioned just prior to unsheathing and deployment.
7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the distal vena cava or iliac vein. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.

   NOTE: The introducer catheter hub has a special internal design. Care should be taken to make connections firmly, but without excessive force that may cause breakage in the hub.
8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for caval thrombi, position of renal veins and congenital anomalies. Select the optimum level for filter placement and measure the IVC diameter, correcting for magnification (typically 20 percent).
9. Advance the introducer catheter to the selected level under fluoroscopic control. The guidewire and dilator should be reinserted to facilitate this. For femoral insertion the introducer catheter tip should be 1 cm below the lowest renal vein.

Filter Delivery

NOTE: Delivery of the *Recovery* Filter through the introducer sheath with the pusher wire is designed as advance-only. Retraction of the pusher wire during delivery can result in dislodgment of the Filter or crossing of the Filter legs or arms and could prevent the Filter from further advancement within the sheath. *Do not pull back on the pusher wire, only advance forward with filter in place.*

10. Remove the filter and delivery system from Kit B.
11. Connect a 500 mL bag of saline to the sideport of the Y-adapter using a standard drip infusion set. Allow the saline infusion to flow around the filter in the storage tube for 5 seconds to soften it for passage through the introducer catheter. Adjust the infusion set to provide a rapid drip rate. Tighten the Touhy-Borst adapter valve to minimize reflux of saline, but not so tight as to prevent the pusher wire from advancing freely.

    NOTE: It is very important to maintain introducer catheter patency with the saline flush so that the grooved segment that holds and properly orients the filter legs does not become clotted over. This will interfere with filter deployment.

12. Attach the free end of the filter storage tube directly to the introducer catheter already in the vein, allowing the saline infusion to flow into the IVC for a few seconds. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.

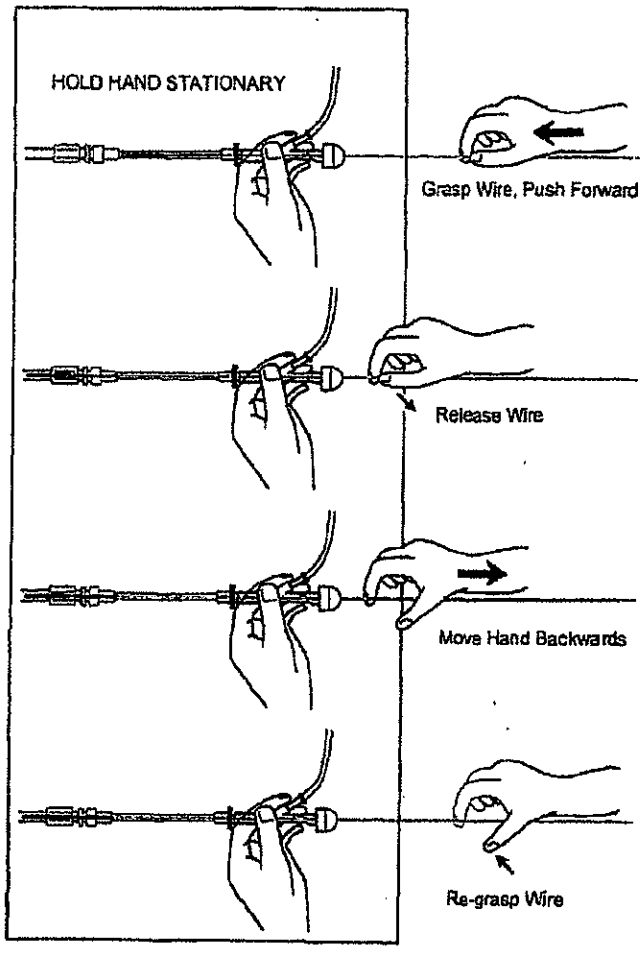
Advancement of Filter, Illustrated

FIGURE B

FIGURE C

FIGURE D

FIGURE E



13. Advance the Filter by moving the nitinol pusher wire forward through the introducer catheter, advancing the Filter with each forward motion of the pusher wire (Figures B-E). *Do not pull back on the pusher wire, only advance the pusher wire forward.* For the operator's convenience, the nitinol pusher wire may be looped, without causing kinking to the nitinol material, to facilitate pusher wire handling and advancement.
14. Continue forward movement of the pusher wire until the Filter tip advances to the radiopaque marker on the distal end of the introducer catheter. At this point, the pusher wire handle should be adjacent to the Y-adapter.

Filter Release/Deployment

15. Deliver and release filter as described below:

Figure F: Firmly hold the pusher wire handle.

Figure F-1: Filter positioned in introducer catheter between the radiopaque markers prior to deployment in IVC.

NOTE: Do not deliver the Filter by pushing it beyond the end of the introducer catheter. Instead, unsheath the stationary Filter by withdrawing the introducer catheter as described below.

Filter Release, Illustrated

FIGURE F

FIGURE F-1

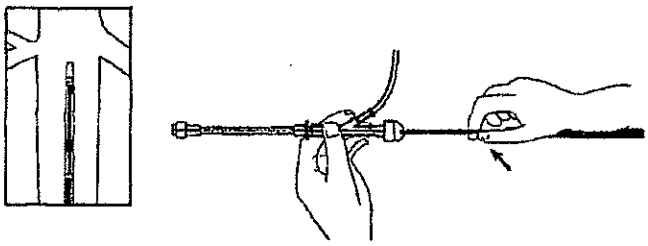


FIGURE G

FIGURE G-1

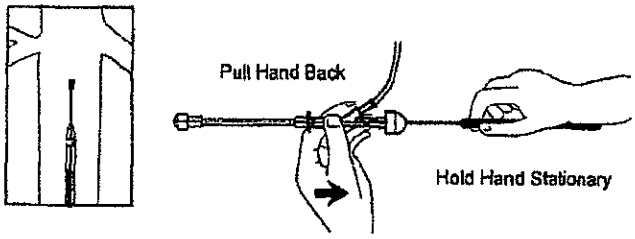
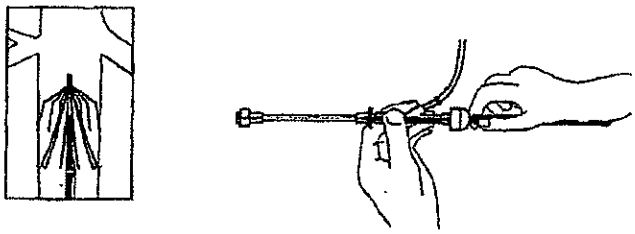


FIGURE H

FIGURE H-1



Now release the Filter by unsheathing it in the IVC as follows:

Position the Filter tip 1 cm below the lowest renal vein.

Figure G: With one hand held stationary, the other hand draws the Y-adapter and storage tube assembly back completely over the handle, uncovering and releasing the filter.

Figure G-1: Unsheathing of Filter in IVC.

Figure H: The position of the hands at the completion of the unsheathing process.

Figure H-1: The Filter deployed in the IVC.

16. Now withdraw the pusher wire back into the storage tube by firmly holding the Y-adapter, storage tube, and delivery catheter assembly and pulling back on the pusher wire.
17. Resume the intermittent saline flush or constant drip infusion to maintain introducer catheter patency.

Follow-up Venacavogram

18. A follow-up venacavogram may be performed after withdrawing the introducer catheter into the iliac vein (typically 30 mL of contrast medium at 15 mL/s).
19. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

OPTIONAL PROCEDURE FOR FILTER REMOVAL:

Removal of Recovery Filter

CAUTION: It is strongly recommended that removal of the Recovery® Filter be done using the Recovery Cone® only.

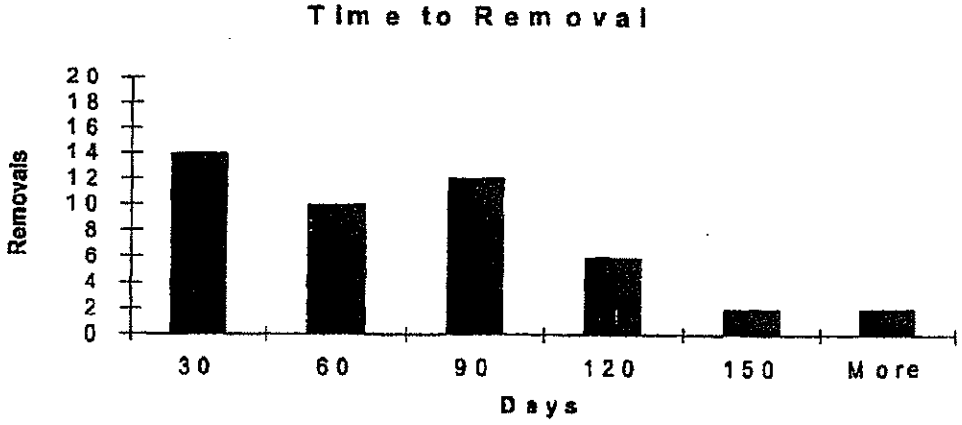
Equipment Required

The following equipment is required for use:

- One *Recovery Cone®* Removal System that contains:
  - One 75 cm, 10 French I.D. delivery sheath and dilator set
  - One Y-adapter with *Recovery Cone* and pusher delivery system
- 0.035" 3 mm J-tipped Guidewire, 110 cm long or longer
- 18 gauge entry needle
- Saline
- Sterile extension tube for saline drip or syringe for saline infusion
- All basic materials for venipuncture: scalpel, #11 blade, local anesthesia, drapes, etc

Clinical Experience

The *Recovery* Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations. Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment. Of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 patients have died with filters in place of causes unrelated to filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days (see histogram).



Follow-up post retrieval has been an average of 325 days (range 1-901 days). Most (n=43) were retrieved via the right internal jugular vein, but some have been via the left internal jugular vein (n=1) and a collateral vein (n=1). One was removed surgically during a cancer operation where the mass was impinging on the filter. The two methods described in the Instructions for Use were used to retrieve the filter in all but 4 cases, when a larger

sheath was used, or a snare loop was attempted instead of using the *Recovery Cone* system. There was one case of asymptomatic pulmonary embolism when using the larger sheath.

The only other adverse event reported was a fractured filter arm and hook. This filter was placed infrarenally in a pregnant woman during the third trimester at the level of L1-L2. The fracture was believed to be secondary to stresses due to delivery and placement infrarenally, causing severe deflection and embedding of the hook into the bony tissue of the vertebrae. The filter was retrieved, minus the hook.

Clinical Experience

Summary Table

Recovery Filters Implanted	58
Percutaneous Filter Removals	45
Surgical Filter Removals	1 (Concurrent to tumor resection)
Patient Age	8-89 years (52 years average)
Reason for filter placement	
Contraindication to anticoagulation	40
Complications associated with anticoagulation	13
Failure of anticoagulation	3
Prophylaxis	2
Time to removal	1-161 days (60 days average)
Follow-up post-removal	1-901 days (325 average)
Filter Removal Complications	
Technical	0
Hook fracture secondary to stresses due to labor and birth and infrarenal placement	1
Asymptomatic pulmonary embolism post-removal	1

Procedural Instructions

Insertion of the Introducer Catheter

1. Select a suitable jugular venous access route on either the right or left side depending upon the patient's size or anatomy, operator's preference or location of venous thrombosis.
2. Prep, drape and anesthetize the skin puncture site in standard fashion.
3. Select and open the *Recovery Cone* Removal System package. Open Kit A Introducer Catheter package.
4. Nick the skin with a #11 blade and perform venipuncture with an 18-gauge entry needle.
5. Insert the guidewire and gently advance it to the location of the *Recovery* Filter for removal.
6. Remove the venipuncture needle over the guidewire. Advance the 10 French introducer catheter together with its tapered dilator over the guidewire and into the vein.

   NOTE: The introducer catheter has a radiopaque marker at the distal end of the catheter sheath to assist in visualization.
7. Remove the guidewire and dilator, leaving the introducer catheter with its tip in the appropriate location. Flush intermittently by hand or attach to the catheter a constant saline drip infusion to maintain introducer catheter patency.
8. Perform a standard inferior venacavogram (typically 30 mL of contrast medium at 15 mL/s). Check for thrombus within the filter. *If there is significant thrombus within the filter, do not remove the* Recovery *Filter.*

Recovery Cone *Insertion and Delivery*

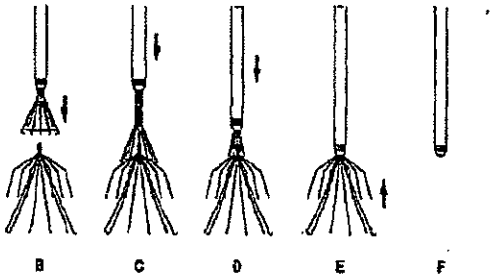
9. Remove the cone and pusher system from Kit B.
10. Flush the central lumen of the cone catheter and wet the cone with saline—preferably heparinized saline.
11. Slowly withdraw the cone into the Y-adapter to collapse the cone.

NOTE: The cone must be fully retracted into the Y-adapter before connecting the system to the introducer catheter to ensure that the cone can be easily delivered through the catheter.

12. Connect a 500 mL bag or a syringe of saline to the sideport of the Y-adapter. Allow the saline infusion to flow around the removal cone in the Y-adapter for 5 seconds. Tighten the Touhy-Borst adapter valve to minimize reflux of saline toward the feeder, but not so tight as to prevent the pusher shaft from advancing freely.
13. Attach the male end of the Y-adapter with the collapsed cone directly to the introducer catheter. The introducer catheter and filter delivery system should be held in a straight line to minimize friction.
14. Advance the cone by moving the pusher shaft forward through the introducer catheter, advancing the cone with each forward motion of the pusher shaft.
15. Continue forward movement of the pusher wire until the cone advances to the radiopaque marker on the distal end of the introducer catheter. Unsheathe to open the cone by stabilizing the shaft and retracting the catheter.

Capture of Recovery *Filter*

Recovery *Filter Removal*



16. The capture of the *Recovery* Filter is illustrated in Figures B-F:

    Figure B: After the cone has been opened superior to the Filter, advance the cone over the Filter tip by holding the introducer catheter stationary and advancing the pusher shaft. It is recommended to obtain an anterior-oblique fluoroscopic image to confirm that the cone is over the Filter tip.

    Figure C: Close the cone over the Filter tip by advancing the introducer catheter over the cone while holding the pusher shaft stationary.

    Figure D: Continue advancing the introducer catheter over the cone until the cone is within the introducer catheter.

    Figure E: With the cone collapsed over the Filter, remove the Filter by stabilizing the introducer catheter and retracting the pusher shaft in one, smooth, continuous motion.

    Figure F: The Filter has been retracted into the catheter.

Follow-up Venacavogram

17. A follow-up venacavogram may be performed after withdrawing the introducer catheter (typically 30 mL of contrast medium at 15 mL/s).
18. Remove the introducer catheter and apply routine compression over the puncture site in the usual way to achieve hemostasis.

Guidewire - Assisted Technique

Due to anatomical variances with respect to the position of the *Recovery* Filter, guidewire assisted techniques may be used.

Use of a Guidewire

If it is difficult to advance the cone over the *Recovery* Filter tip, one may use a guidewire to facilitate advancement of the cone over the Filter tip.

Withdraw the introducer sheath and *Recovery Cone* shaft away from the Filter tip. Insert a 0.035" guidewire through the central lumen (J-tipped or angled tip; a hydrophilic-coated guidewire is recommended). Advance the guidewire through the cone and through the Filter near the Filter tip.

After it has been confirmed that the guidewire is in contact with or in close proximity to the Filter tip, advance the cone over the guidewire to the Filter tip.

Advance the introducer sheath to slightly collapse the cone over the Filter tip. Withdraw the guidewire into the pusher shaft.

Continue removing the Filter as described in step 16.

J. How Supplied

Each *Recovery* Filter is supplied preloaded in its storage tube. Each *Recovery* Filter is sterile and nonpyrogenic unless package is damaged or opened, and is ready to be ***used for a single use only.*** The storage tube and delivery system are pre-assembled. If the filter is inadvertently discharged, ***do not attempt to re-sterilize or reload it.***

Note: After use, the *Recovery* Filter accessories and insertion supplies may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

This Product should be stored in a cool (room temperature), dry place.

K. Warranty

Bard warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in Bard's sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL **BARD** BE LIABLE TO YOU FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some states/countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your state/country.

Labeling Issue Date:

In the event 3 years have elapsed between this date and product use, the user should contact C. R. Bard, Inc. to see if additional product information is available.
(Inside U.S.: 1-800-321-4254; Outside U.S.: 1-480-894-9515)

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CE
0086

Bard Peripheral Vascular, Inc.
Tempe, AZ 85281
Inside U.S.: 1-800-321-4254
Outside U.S.: 1-480-894-9515

EEA Authorized Representative:
Bard Limited
Crawley, UK
RH11 9BP

EXHIBIT 42

Detachment Severity	1	2	3	4	5	6
Complaint No.	Special Access Pt #13	6103120044	3104020049	2588	3088	3284
Complaint Category	B	B	B	B	B	A
Research	NL Sinai Hospital	Northwest Regional Hospital	Scripps Mercy Hospital	Mease Countryside Hospital	Oregon Health Science University	Baptist Memorial Hospital East
Research Address	Toronto, Canada	Margate, FL	San Diego, CA	Safety Harbor, FL	Portland, OR	Memphis, TN
Physician	Dr. Murray Asch	Dr. Julian	Dr. Kevin Sasaduisz	Dr. Jerry Niezwecki	Dr. John Kaufman	Dr Phillip Zeni
Sales Rep	N/A	P. MacDonald	C. Goodrow	John Buckley	Kathleen Spegar	Jason Greer
Sample returned	Yes-at NMT	No. Retained at Hospital	No. Retained at Hospital	Yes. CMP 12571	Attempted filter removal unsuccessful, filter remains implanted	No, Retained at Hospital
Date of Implantation	1/31/2002	10/20/2003	11/20/2003	10/27/2000	12/1/2003	10/2003
Date of Event	4/16/2002	12/20/2003	2/23/2004	3/17/2004	3/23/2004	4/7/2004
Date Reported to Bard	2/18/2002	12/22/2003	2/24/2004	3/17/2004	3/23/2004	4/7/2004
Time With Implanted	N/A	1/21/2004	3/18/2004	4/13/2004	4/23/2004	5/11/2004
Lot No.	108142	Unknown	07ON3555	07HH2269	07HH0279	Unknown
Filter Indication	Pregnancy	Unknown	Unknown	Prophylactic	Unknown	Prophylaxis
Case Pt. History	Detached arm noted after the patient delivered a baby.	Unknown	Unknown	Filter placed for bariatric procedure - open gastric bypass procedure.	Unknown	Patient was in ICU for a long period of time before this procedure. Patient had numerous venous lines in and out during course of treatment
Pt. Age at Time of Event	29	Unknown	65	29	21	Unknown
Sex	F	Unknown	M	F	Unknown	F
Pt. Ideal Height	Unknown	Unknown	Unknown	286 lbs / 5'4"	Unknown	Unknown
Normal Placement?	Yes	Unknown	Unknown	Unknown	Unknown	Unknown
Post Implant Symptoms		Unknown	Unknown	Unknown	None	Unknown
Diagnostic Imaging	CT Scan	Unknown	Vena Cava gram	Vena Cava gram	Vena Cava gram	Unknown
Days to Detachment	51	61	65	141	111	183
Incidental Finding?	Yes	Yes	Yes	Yes	Yes	Yes
Location of limb on X-ray/CT/etc	1-Arm projected above filter, tip adjacent to rt renal vein. Filter tilted right, hooks not visible	1- Detached arm seen on K-ray slightly above filter just prior to filter removal.	1- Detached arm seen on K-ray in Right Renal Vein just prior to removal of filter.	2 Arms seen perpendicular to the cave wall, adjacent to the filter.	1 Detached arm in body, unknown location	1-Detached arm in Cava wall, above the Renals
Location of Limb Post Removal	Detached arm and filter removed successfully. 1-Hook missing. Not seen on CT	Detached arm and filter removed successfully	1 Arm remains in Right Renal Vein	3 Arms were detached at removal. All were removed with the filter. 1 hook from one leg is missing.	1 Detached arm remains in body, 1 location	1- Detached arm remains in Rt. Ventricle
Cave Size	24mm	Unknown	Unknown	28.9 mm	Unknown	Unknown
Patient Outcome	"Pt is in good condition"	Filter and arm removed, no pt injury	Unknown	Filter removed, 1 hook missing. No patient injury reported.	Asymptomatic	Normal heart rhythm. 1 arm in Rt. Ventricle. Dr Zeni consulted with Dr. Kaufman. Both doctors agreed: No retrieval needed.
Filter Removed on	4/16/2002	12/20/2003	2/24/2004	3/17/2004	Filter remains implanted	4/7/2004
Filter	CT Scan	Yes	Yes	Yes	No	No. Photos
Retrieval Successful	(1) Hook	None	(1) Arm	(1) Hook	(1) Arm	(1) 21.6mm Arm

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Recovery Filter Detached Limbs - Patient Comparison Matrix
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Detachment / Mortality	7	8	9	10	11	12
Complaint No.	6970	6971	7288	10436	10609	11168
Complaint Category	B	B	A	B	B	A
Account	St Luke Episcopal Hospital	St Luke Episcopal Hospital	Milton Hershey Medical Center	Santa Clara Valley Medical Center	Methodist Hospital	John Peter Smith Hospital
Account Address	Houston, TX	Houston, TX	Hershey, PA	San Jose, CA	Dallas, TX	Fort Worth, TX
Physician	Dr. Barry Toombs	Dr. Barry Toombs	Dr. Frank Lynch	Dr. Lebowitz	Dr. Ken Kollmeyer	Dr. Siddiqi
Sales Rep	Nancy Baklik	Nancy Baklik	Scott Hughes	Nikki George	Brooke Gillette	Brooke Gillette
Sample returned	Yes, CMP 12915	Yes, CMP 17914	Yes, CMP 12895	Yes, CMP 13136	Yes, CMP 13147	Yes, CMP 13365
Date of Implantation	2/25/2004	5/17/2003	8/2/2003	Mar-04	Apr-04	4/16/2004
Date of Event	4/25/2004	10/24/2003	4/27/2004	5/19/2004	5/21/2004	6/2/2004
Date Reported to Bard	4/25/2004	4/26/2004	4/27/2004	5/20/2004	5/27/2004	6/?/2004
Date MDR Submitted	5/24/2004	5/24/2004	5/21/2004	6/21/2004	6/14/2004	5/21/2004
Lot No.	07KN2847	07DN0664	Unknown	Unknown	Unknown	GF083102
Filter Indication	Unknown	Unknown	PE	Pt in halo traction	Prophylactic	Prophylactic
Other Pt. History	Unknown	Unknown - This was first event for this account. Second incident (6970) prompted this report to us.	Admitted Sept 2003 for intracranial seizures, during hospital stay developed PE and filter was placed. Pt had emergency Lap. Cholecystectomy 2 weeks prior to filter removal	Patient is paralyzed from neck down	Filter placed prior to gastric bypass surgery	Trauma Pt., Auto Accident
Pt. Age at Time of Event	Unknown	Unknown	29	18	Unknown	17
Sex	Unknown	Unknown	F	F	F	M
Wt (lbs)/ Height	Unknown	Unknown	Unknown	115 lbs	500 lbs	Unknown
Normal Placement?	Unknown	Unknown	Yes	Unknown	Unknown	Yes
Post Implant Symptoms	Unknown	Unknown	None	None	None	Pain on removal
Diagnostic Imaging	Vena cava gram	Vena cava gram	Vena Cava Gram	Vena Cava Gram	Unknown	Vena Cava Gram
Days to Detachment	60	129	237	60	30	47
Incidental Finding?	Yes	Yes	Yes	Yes	Yes	Yes
Location of limb on X-ray/Initial	Hook not seen on X-ray	Hook not seen on X-ray	1- Arm perpendicular to the cava wall	1-Arm seen moving up and down in cava when the pt inhaled and exhaled.	Unknown	1-Arm in right middle lobe of lung, 1 Arm location unknown
Location of Limb Post Removal	One missing hook from leg not seen on X-ray	One missing hook from leg not seen on X-ray	1- Arm is firmly attached to cava wall below renals. 1 arm was seen on films in right lung.	Detached Arm was removed in the Recovery Cone when the filter was removed.	1- missing hook from leg not seen on X-ray	1-Arm snared and removed from lung. 1- arm, location unknown (reported as maybe dropped on the floor)
Cava Size	Unknown	Unknown	Unknown	Unknown	Unknown	22-22mm
Patient Outcome	Asymptomatic	Asymptomatic	Asymptomatic	Asymptomatic	Asymptomatic	Filter removed on 6/23 by Dr. Rivera
Filter Removed/Date	4/28/2004	10/24/2003	4/27/2004	5/19/2004	5/21/2004	6/23/2004
Films	No	No	Yes	Yes	No	Yes
Retained Segment	(1) 3.6mm Hook	(1) Hook	(2) Arms	None	(1) Hook	Possibly (1) Arm

Recovery Filter Detached Limbs - Patient Comparison Matrix
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Detachment # (Monthly)	13	14	15	16	17	18
Complaint No.	11596	12847	12848	12934	13530	15041
Complaint Category	B	A	B	A	A	B
Account	McKay Dee Hospital	Medical College of Ohio	Mercy General Hosp	Memorial Health Univ Med. Ctr.	Christiana Hospital	Santa Clara Medical Center
Account Address	Ogden, UT	Toledo, Ohio	Muskegon, MI	Savannah, GA	Newark, DE	San Jose, CA
Physician	Dr. Paul Sonnay	Dr. Munier Nazzal	Dr. David Kaufman	Dr. Jerry Cohn	Dr. Mark Garcia	Dr. Morrison
Sales Rep	Ben Haygood	Nika Timco	Dave Bourbeau	Melanie Vitaco	Scott Hughes	Nikki George
Sample returned	Yes, CMP 13260, Sample missing 1 arm & 1 hook	NO	No	No	Yes, CMP 13564	Yes CMP 13500
Date of Implantation	Nov-03	Jan-04	4/2/2004	12/22/2003	May-04	Apr-04
Date of Event	6/9/2004	6/17/2004	6/21/2004	6/21/2004	6/30/2004	7/12/2004
Date Reported to BMD	6/9/2004	6/17/2004	6/21/2004	6/21/2004	6/30/2004	7/14/2004
Date MDR Submitted	7/8/2004	7/16/04	7/20/04	7/20/04	7/28/2004	8/11/2004
Lot No.	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Filter Indication	Prophylactic	Prophylactic	Prophylactic	Anticoagulants contraindicated	PE post pelvic surgery	Prophylactic
Other Pt. History	Trauma Pt. Bilateral Femoral fractures, Pelvic Fracture	Patient was in a motor vehicle accident. Multiple injuries	Pt. had gastric bypass surgery after filter placement in Apr. 2004	GI Bleeding	Pt event occurred during Yoga session	Post Spinal Cord Injury
Pt. Age at Time of Event	17	15	38	Unknown	53	Unknown
Sex	F	F	F	Unknown	F	Unknown
Wt. lbs/ Height	108 lbs	Unknown	425 lbs	Unknown	Unknown	Unknown
Normal Placement?	Yes	Yes	Yes	1 leg "slightly angulated", 1cm below left renal.	Unknown. Filter placed at Graduate Hosp PA	Unknown. Filter placed at another hospital
Post Implant Symptoms	None	None	None	Chest Pains "unrelated to arm detachment"	SOB, "Passed out", cardiac arrhythmia, bleeding into pericardium	None
Diagnostic Imaging	Vena Cava Gram	X-Ray	Vena Cava Gram	CT	Cardiac Cath /Chest X-ray	Cava Gram
Days in Detachment	215	152	80	181	61	92
Incidental Finding?	Yes	Yes	Yes	Yes ?	No	Yes
Location of limb on X-ray (initial)	1- Arm Embedded in cava wall, 2cm above the filter	2- Arms noted to be pointed up, parallel to cava wall just prior to removal.	2- Arms bent upwards, and filter was slightly tilted caudally	1-Arm in Right ventricle	1-Arm "punctured heart wall"	1-Leg seen on X-ray, tilted at a 30 degree angle. Filter was not tilted.
Location of Limb Post Removal	1- Arm Embedded in cava wall, 2cm above the filter.	2- Arms "in the pulmonary circulation"	1- Arm detached and removed with the filter. 1-arm embedded in vena cava, below the renals	Unsuccessful filter (not arm) removal on 6/30. 1- arm remains in rt. Ventricle	Detached arm surgically removed from heart prior to percutaneous filter removal	All limbs removed with filter in tact. 1-Hook missing
Cava Size	Unknown	Unknown	Unknown, but "on upper limits of normal"	Unknown	Unknown	Unknown
Patient Outcome	Asymptomatic	Patient is asymptomatic. No bleeding, no arrhythmias	Asymptomatic	Etiology of chest pains unknown. Pt. is currently fine.	Had open heart surgery on 6/30 to remove the arm. 1-4 hours later, tilted filter was removed with difficulty	Asymptomatic
Filter Removal Date	6/9/2004	6/17/2004	6/21/2004	Unsuccessful removal, remains implanted	7/1/2004	7/12/2004
Filter	Yes	No	No	Yes	Yes	Yes
Retained Segment	(1) Arm, (1) Hook	(2) Arms	(1) Arm	Filter, (1) Arm	None	1-Hook

Submitted / Worksite	19	20	21	22	23	24
Complaint No.	19379	19999	19458	19627	20308	21216
Complaint Category	B	A	B	B	B	B
Account	West Allis Memorial Hospital	University Community Hospital	DCH Regional Medical Center	Medical College of Georgia	Geisinger Medical Center	University Hospital of Cleveland
Account Address	West Allis, WI	Tampa, FL	Tuscaloosa, AL	Augusta, GA	Danville, PA	Cleveland, OH
Physician	Dr. Peter Drescher	Dr. Kelly VanEpps, IR Brenes Alva, Cardiac Surgeon	Dr. Byron Speed	Dr. Bill Bates identified the fracture His partner implanted the filter	Dr. James Elmore	Dr Adam Blum
Salesrep	Tim Fischer	John Buckley	Rob Williamson	Melanie Vitese	Larry Kebs	Michael Guzzo
Records Returned	Yes, Cli? 13515	No, patient's spouse retained the detached wire	Yes	No	Remains implanted	Yes
Date of Implantation	May-04	4/5/2004	2/11/2004	Apr-04	2/18/2004	Mar-04
Date of Event	7/13/2004	8/10/2004	8/24/2004	8/2/2004	9/2/2004	Jun-04
Date Received at Bard	7/15/2004	8/16/2004	8/25/2004	8/27/2004	9/2/2004	9/2/2004
Date MDR Submitted	8/11/2004	9/9/2004	9/23/04	9/23/04	10/1/2004	10/1/2004
Lot No.	Unknown	Unknown	Unknown	Unknown	07N3472	Unknown
Filter Indication	Explanting doctor did not know	Unknown	Prophylactic prior to knee surgery	DVT	Prophylactic prior to orthopedic surgery on leg	DVT
Other Pt. History	Unknown. The explanting doctor did not implant the filter	Filter was explanted on 8/24/04 Patient returned to the hospital August 10 with blood in the pericardium, and a wire in the heart.	Motor Vehicle accident - multiple trauma	C-Section 5 months ago. Returned to hospital in Aug. with invasive cervical CA, and blocked ureters. Insertion of bil. Nephrostomy tubes.	Cranial Trauma	History of DVT
Pt. Age at Time of Event	Unknown	34	24	31	19	Unknown
Sex	Unknown	F	M	F	M	Unknown
Wt (lbs) at Event	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Normal Placement?	Unknown. Filter placed by another doctor	Yes	Unknown	Pt. had clot in cava at time of placement. Filter had to be placed above the renals	Yes	Yes. Placed 1cm below lowest renal vein
Post Implant Symptoms	None	Symptomatic	None	None filter related	None filter related	Unknown
Diagnostic Imaging	Cava Gram	CT	Cava Gram	CT	Cava Gram	Cava Gram
Days to Detachment	81	127	194	122	98	91
Migration? Fracture?	Yes	No	Yes	Yes	Yes	Yes
Location of Limb in X-ray, Notes	1-Leg seen on X-ray broken 1/3 way down shaft	2.3 cm length of wire with a 30 degree bend seen in the heart	Not seen	1- Detached leg in bony vertebrae	Slightly tilted filter with detached arm	Filter was 4 cm below right atrium
Location of Limb Post Removal	2/3 of leg remains embedded in cava wall	Unknown	1- missing hook from leg not seen on X-ray	Filter remains implanted, 1-Leg in bony vertebrae	Filter remains implanted, 1-Detached arm in cava wall next to filter	1- Detached hook not found
Clot Size	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Patient Outcome	Asymptomatic	Percutaneous removal unsuccessful. Sternotomy performed 8/10/04 to remove the "blue" wire.	Asymptomatic	Asymptomatic, Dr did not inform pt about detachment	Dr unable to remove filter. Pt asymptomatic	Unknown
Filter Removal Date	7/13/2004	8/24/2004	8/24/2004	Remains implanted	Remains implanted	Jun-04
Fibrin	Yes	Yes	Yes	Yes	Yes	None
Retained Segments	2/3 Leg	None	(1) Hook	Filter, (1) Detached leg	Filter, (1) Arm	(1) Hook

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Recovery Filter Detached Limbs - Patient Comparison Matrix
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Detachment / Mortality	25	26	27	28	29	30
Complaint No.	21960	23188	24046	24514	25351	26181
Complaint Category	B	A	B	B	B	B
Account	Porter Adventist Hospital	Univ. CA at Davis	St. Joseph's Hospital	Sheffield Teaching Hospital	Hartford Hospital	University of Cleveland Hospital
Account Address	Denver, CO	Sacramento, CA	Tampa, FL	Sheffield, UK	Hartford, CT	Cleveland, OH
Physician	Dr. Dominic Yee	Dr. Ortiz	Dr. Glen Stambo	Trevor Cleveland	Dr. Dominique Zambuto	Dr. Mark Sands
Sales Rep	Ben Haygood	Alison Walsh	John Buckley	Darren Barlow	Zack Houde	Mike Guzzo
Device Returned	Yes	No	Yes	Yes	No	No
Date of Implantation	7/11/2004	Jan-04	4-6 months prior to event	Unknown	8/11/2004	8/20/2004
Date of Event	8/17/2004	9/30/2004	10/8/2004	10/7/2004	10/22/2004	10/29/2004
Date Reported to Bard	8/17/2004	9/30/2004	10/11/2004	10/11/2004	10/22/2004	10/29/2004
Date MDR Submitted	10/14/2004	10/26/2004	11/9/04	11/10/2004	11/18/04	11/22/2004
Lot No.	Unknown	07JN0105	Unknown	Unknown	07I0H2570	GFDO3401
Filter Indication	DVT	Prophylactic, Trauma Pt.	Prophylactic	Prophylactic for an orthopedic procedure	Risk of DVT due to extensive vein compression from pregnancy	Risk of DVT - Pregnancy
Other Pt. History	Knee Surgery	Pt. was in abdominal restraints while in the hospital	Lysis of iliac clot	History of DVT and PE	Filter placed when pt. was 8 months pregnant. Pending ? Vaginal delivery or C-Section	Vaginal Delivery Post Filter placement
Pt. Age at Time of Event	Mid 20's	40	42	Unknown	16	30
Sex	F	F	F	F	F	F
Weight/Height	Unknown	Unknown	Unknown	Unknown	145 lbs	Unknown
Normal Placement?	Yes	Yes	Yes	Yes	Infra-Renal placement	Placed below the Renals
Post Implant Symptoms	None	Chest Pains	None	None	None	None
Diagnostic Imaging	Cava Gram	CT	CT	Cava Gram	Cava gram/CT	Cava Gram
Days to Detachment	68	244	4-6 Months	Unknown	72	130
Incidental Finding?	Yes	No	Yes	Yes	Yes	Yes
Location of limb on X-ray/image	Apex of Filter tilted and tightly against cava wall	Heart	1 arm could not be seen on CT in abdomen or chest	Arm pointing cephalad, parallel to cava wall	1-Leg detached from filter seen on Cava gram next to filter ? location missing hook	1 - Detached arm in cava wall near the filter
Location of Limb Post Removal	1 - Detached hook not found	Arm removed surgically from heart	1 - Arm missing. Location? Dr. states the arm could not be seen on initial placement films.	All parts removed	1- Detached Leg reported as "migrated" Location-cava- vein side branch	1 - Detached arm in cava wall near the filter. Filter remains implanted
Cava Size	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Patient Outcome	Asymptomatic	Asymptomatic	Asymptomatic	Fine	Asymptomatic	Asymptomatic
Filter Removed/Date	9/17/2004	Remains implanted	10/8/2004	10/7/2004	Remains implanted	Remains implanted
Films	Yes	Yes	Yes	Yes	Yes	Yes
Returned Specimen	(1) Hook	Filter minus (1) Arm	(1) Arm	None	(1) Leg, (1) Hook	Filter, (1) Detached Arm

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Recovery Filter Detached Limbs - Patient Comparison Matrix
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Detachment/Mortality #	31	32	33	34	35	36
Complaint No.	26217	26298	30291	30157	31380	31365
Complaint Category	A	B	A	B	B	B
Account	Mesa General Hospital	Washoe Medical Center	Mass General Hospital	Univ. of PA	Cleveland Clinic	Univ. Medical Center
Account Address	Mesa, AZ	Reno, NV	Boston, MA	Philadelphia, PA	Cleveland, OH	Las Vegas, NV
Physician	Dr. Echauser	Dr. John Hanson	Dr. Stephen Wicky	Jeffrey Solomon	Edwardo Chranwald	Unknown
Sales Rep	Kevin Haslem	Alison Walsh	Paul Bonsara	Hugh McGee	Mike Gutzo	Brad Hasna
Sample returned	No	Yes	No	Yes	Yes	Yes
Date of Implantation	Unknown	9/1/2004	2003	2004	10/5/2004	7/19/2004
Date of Event	10/28/2004	11/1/2004	12/9/2004	Unknown	12/17/2004	12/17/2004
Date Reported to Bard	10/29/2004	11/1/2004	12/9/2004	12/15/2004	12/23/2004	12/17/2004
Date MDR Submitted	11/19/2004	11/29/2004	1/5/2005	1/12/2005	1/17/2005	1/14/2005, 1/19/2005
Lot No.	Unknown	GFOC2585	Unk	Unknown	Unknown	Unknown
Filter Indication	Unknown	Prophylactic-Trauma	Pelvic Trauma	Unknown	Unknown	Trauma
Other Pt. History	Filter was placed in a hospital out of state. Dr didn't know any patient history.	Trauma to Liver and Spleen. In ICU post filter placement	Pelvic Surgery prior to filter placement	Unknown	Unknown	Unknown
Pt. Age at Time of Event	Unknown	60	Unknown	Unknown	59	Unknown
Sex	Unknown	F	M	Unknown	F	M
Wt (lbs)/Height	Unknown	145 lbs	Unknown	Unknown	Unknown	Unknown
Femoral Placement?	Unknown	Unknown	Unknown	Unknown	Yes	Unknown. Placed at another hospital
Post Implant Symptoms	None	None	None	None	None	None
Diagnostic Imaging	Cava Gram	Cava gram	CT	Cava gram	Cava gram	Cava gram
Days in Detachment	Unknown	62	Unknown	Unknown	39	151
Incidental Finding?	Yes	Yes	Yes	Yes	Yes	Yes
Location of limb on X-ray/Initial	On/near the filter	1- Detached arm outside of the cava, attached to cava wall near the filter	1-Detached leg in cava wall. 1-Detached leg in the head of the pancreas.	1-Detached arm in the filter apex 1cm below the renals	Next to filter in the original placement location	Unknown
Location of Limb-Post Removal	1- Detached Arm in Left Pulmonary Artery	1- Detached arm outside of the cava, attached to cava wall near the filter	Same as above. Additional attached leg perforated the cava wall	Detached arm removed in Dec 2004. Filter successfully removed 3/22/2005. Sample returned, found with 1 missing arm and 3 hooks.	Detached arm and Filter removed. Hook missing	1- Detached Limb was removed with a snare after Filter was removed
Cava Size	Unknown	"Normal"	Unknown	Unknown	Unknown	Unknown
Patient Outcome	Asymptomatic	Asymptomatic	Currently fine	Unknown	Asymptomatic	Asymptomatic
Filter Removed/Date	10/29/2004	11/1/2004	Remains implanted	3/22/2005	12/17/2004	12/17/2004
Fixes	None	Yes	No	No	Yes	No
Returned Segment	(1) Arm	(1) Arm, (1) Hook	Filter, (2) Detached legs	Possible (3) Hooks	(5) Hook	None

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Recovery Filter Detached Limbs - Patient Comparison Matrix
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Detachment / Mortality	37	38	39	40	41	42
Complaint No.	34982	32442	33340	34006	34683	34684
Complaint Category	A	A	B	A	A	A
Account	St Joseph's Mercy Hosp.	St Joseph's Med Center	Berkshire Medical Center	St Rita's Med Center	Advocate Christ Med Ctr	University of Chicago
Account Address	Ypsilanti, MI	Phoenix, AZ	Pittsfield, MA	Lima, Ohio	Oak Lawn, IL	Chicago, IL
Physician	Michael Sarosi	Philip Lenaze	Kevin McDonnell	Pavan Pynukolu	Martin Borhani	Brian Funaki
Sales Rep.	Dave BouBeau	Kevin Heslam	Zach House	Jennifer Keener	Tim Ridinger	Tim Ridinger
Sample returned	No	Yes	No	Yes	No	No
Date of Implantation	Feb-04	4/25/2004	10/14/2004	9/14/2004	6/25/2004	Unknown
Date of Event	12/27/2004	12/23/2004	1/14/2005	1/20/2005	1/26/2005	Unknown
Date Reported to Bard	12/27/2004	1/4/2005	1/14/2005	1/20/2005	1/28/2005	1/27/2005
Date MDR Submitted	1/24/2005	1/31/2005	1/31/2005	2/8/2005	2/25/2005	2/25/2005
Lot No.	Unknown	07DN3658	Unknown	GFDE1579	Unknown	Unknown
Filter Indication	Trauma	DVT	Bilateral Pulmonary Emboli	Recurrent PE	Prophylactic	Unknown
Other Pt. History	Unknown	Brain Tumor, Hypertension, Cranial aneurysm clipping	Unknown	Dr. stated he felt the filter was in the right atrium for 1 month	Gastric Bypass surgery, December 2004	Unknown
Pt. Age at Time of Event	30's	58	57	45	52	Unknown
Sex	M	F	M	F	F	Unknown
Wt./Ht.	190 lbs	Unknown	Unknown	"Average Build"	Morbidly Obese, 350 lbs	Unknown
Normal Placement?	Unknown	Unknown	Yes, at L1-L2	Yes	Yes	Unknown
Post Implant Symptoms	None	Abdominal Pains since filter implant (none since filter removal)	None	Chest Pain	Chest Pains, Weakness, Vomiting	Unknown
Diagnostic Imaging	Cava gram	Cava gram	Cava gram	CT	Chest X ray	Unknown
Days to Detachment	305	181	92	128	215	Unknown
Incidental Finding?	Yes	No	Yes	No	No	Yes
Location of limb on X-ray/initial	All components were on the filter prior to removal attempt	1-Arm detached, next to filter in the vena cava	1-Leg detached, perforating cava wall. Filter had migrated 4cm cranial	Filter had migrated to the right atrium. 1 Location of 1- Hook	1- Arm in Right Lung. Hematoma around segment in lung	1-Arm detached and now in rt. lower lobe of lung
Location of Limb-Post Removal	1 Arm in each lung	1- Arm detached, next to filter in the vena cava. 1- Arm in the lung ? Hook	1- Leg Removed with Snare	Unknown location of Hook	1-Arm in right lung at autopsy	1-Arm detached and now in rt. lower lobe of lung. Filter remains implanted
Cava Size	Unknown	Unknown	Unknown	14.7 mm at implant, 23.7mm on 1/20/05	Unknown	Unknown
Patient Outcome	Asymptomatic	Unknown	Asymptomatic	Patient had open heart surgery to remove the filter. Asymptomatic post removal.	Death	Unknown
Filter Removed/date	12/27/2004	12/23/2004	Remains implanted	Yes, 1/21/2005	At autopsy	Remains implanted
Films	Yes	No	None	No	No	No
Retained Segment	(2) Arms	(2) Arms, (1) Hook	Filter minus (1) Leg	(1) Hook	None	Filter, (1) Detached Arm

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LMD1

Recovery Filter Detached Limbs - Patient Comparison Matrix
CONFIDENTIAL

[illegible]	43	44	46	44	47	48
Complaint No.	35877	36068	36371	37155	37335	39541
Complaint Category	B	A	A	B	B	A
Account	Cornell University Hospital	Christiana Hospital	Reading Hospital	Evanston Hospital	Northwest Regional Hospital	Cornell Univ Medical College
Account Address	New York, New York	Newark, Delaware	Reading, PA	Evanston, IL	Margate, FL	New York, NY
Physician	David Trost	Mark Garcia	Robert Guay	Frank Facchini	Wilian Julien	David Trost
Sales Rep	Barry Broggy	Tex Camden	Tex Camden	Doug Kaufman	Marie Scorcs	Barry Broggy
Sample returned	No	No	No	Yes	Yes	No, remains implanted
Date of Implantation	2/23/2004	11/12/2004	10/27/2004	8/9/2004	10/1/2004	Feb 2004
Date of Event	1/25/2005	2/1/2005	2/14/2005	2/14/2005	2/21/2005	Sept 2004
Date Reported to Bard	2/8/2005	2/9/2005	2/14/2005	2/18/2005	2/22/2005	3/11/2005
Date MDR Submitted	3/8/2005	3/9/2005	3/14/2005	3/15/2005	3/24/2005	3/25/2005
Lot No.	Unknown	GFOF0515	07KN2854	GFOC4560	07KN2157	Unknown
Filter Indication	PE	DVT	Prophylactic	Prior to Knee Surgery	DVT	Unknown
Other Pt. History	Unknown	DVT, Bilateral Lower Extremities, Hip Fracture	Unknown	Excellent Condition/Football player	Gastric Bypass Surgery	Cancer, DVT, PE, prior retrievable filter implanted and removed successfully (details unknown)
Pt. Age at Time of Event	46	80	58	21	40	26
Sex	M	F	F	M	F	F
Pt. Size/Height	Unknown	Unknown	Morbidly Obese 329 lbs	Unknown	Morbidly Obese	"not obese"
Normal Placement?	Yes	Yes	Unknown	Yes	Yes	Unknown
Post Implant Symptoms	None	Unknown	Unknown	None	No	Unknown
Diagnostic Imaging	Cava gram	Cava gram	Cava gram	Cava gram	Cava gram	Yes
Days to Detachment	336	79	110	189	122	180
Incidental Finding?	Yes	Yes	Yes	Yes	Yes	Yes
Location of Limb on X-ray/Initial	1-Leg noted 5mm above the filter	2-Arms in Right Ventricle	1-Arm in the cava wall, 1-Arm in the tricuspid valve	1/2 of a leg in cava wall, next to filter	1-Arm in Pulmonary Artery	1-Arm in Right Atrium
Location of Limb-Post Removal	Removed on 1/25/05	2-Arms in Right Ventricle, Filter remains implanted	1-Arm in the cava wall, 1-Arm in the tricuspid valve	1/2 of a leg in cava wall	1-Arm in Pulmonary Artery	1-Arm in right atrium, filter remains implanted
Cava Size	16mm	Less than 20mm	14mm	Unknown	"Normal"	Unknown
Patient Outcome	Asymptomatic	Unknown	Unknown	Asymptomatic	Unknown	Unknown
Filter Removed/Date	2/8/2005	Unsuccessful removal, remains implanted	2/14/2005	2/18/2005	2/21/2005	Remains implanted
Films	Pending	No	Pending	Yes	Yes	Doctor is sending films
Returned Product	None	Filter, (2) Detached Arms	(2) Arms	(1/2 of 1) Leg	(1) Arm	Filter, (1) Detached Arm

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Recovery Filter Detached Limbs - Patient Comparison Matrix
CONFIDENTIAL

Detachment # (Monthly)	49	50	51	52	53	54
Complaint No.	40395	41179	41705	43608	44511	45485
Complaint Category	A	A	A	B	A	B
Account	Hospital Charles-Lemoyne	Mercy Health System	Henry Ford Hospital	Pitt County Memorial Hospital	Parkland Memorial Hospital	North Fulton Regional Hospital
Account Address	Greenfield Park, QC Canada	Darby, PA	Detroit, MI	Greenville, NC	Dallas, TX	Roswell, GA
Physician	Dr. Martin Francoeur	Dr. Simmons	Dr. Adam Greenbaum	Dr. Chris Thomas	Dr. Jorge Lopez	Dr. Daye Byrd
Sales Rep	Guy Ringuette	Hugh Magee	John Timko	Brett Hickman	Brooks Gillette	Bill Cleary
Sample Returned	No	No	No, remains implanted	No		
Date of Implantation	6/18/2004	12/23/2004	Feb 2005	4/8/2004	Unknown	June 2004
Date of Event	3/21/2005	3/30/2005	4/5/2005	4/22/2005	Unknown	3/12/2005
Date Received by Bard	3/22/2005	3/30/2005	4/5/2005	4/22/2005	5/12005	5/12/2005
Date MDR Submitted	4/21/2005	BPV to submit on 4/29/2005	4/11/2005	5/20/2005	5/26/2005	6/3/2005
Lot No.	GF0B2312	GFOF0603	Unknown	GFOB3102	Unknown	Unknown
Filter Indication	Polytrauma patients not responsive to anticoagulotherapy	Unknown	Prophylactic	Multiple trauma from MVA	Unknown	Pregnancy, DVT
Other Pt. History	None other than Polytrauma	Unknown	Kidney replacement patient, numerous pic lines and catheters placed during indwell period.	Unknown	Unknown	Patient gave birth during indwell period
Pt. Age at Time of Event	25	28	30	50	Unknown	Unknown
Sex	M	F	F	F	Unknown	F
Wt and Height	Unknown	Unknown	140 lbs / 5'6"	"Normal"	Overweight, not morbidly obese	Unknown
Normal Placement?	Unknown	Unknown	Yes	Yes	Yes	Yes
Post Implant Symptoms	Unknown	Unknown	None	Asymptomatic	Unknown	Asymptomatic
Diagnostic Imaging	Yes, fluoro angio	Yes	Chest scan	Yes	CT	Cava-gram
Days to Detachment	274	97	56	370	Unknown	330
Incidental Finding?	Yes	Yes	Yes	Yes	Unknown	Yes
Location of limb on X-ray/initial	1-Limb separating from filter upon removal	1-Arm in right pulmonary artery	1-Arm in renal vein, 1-Arm in iliac	Unknown	Unknown	1-Arm attached to caval wall
Location of Limb Post Removal	1-Limb in lung, successfully retrieved	1-Arm in right pulmonary artery	1-Arm in renal vein, 1-Arm in iliac, filter remains implanted	1-Hook, unknown location	Multiple (4) detached limbs, filter migrated 2cm	1-Arm removed with snare
Cava Size	Unknown	Unknown	Unknown	> 28mm	Unknown	Unknown
Patient Outcome	Asymptomatic	Asymptomatic	Asymptomatic	Asymptomatic	Asymptomatic	Asymptomatic
Filter Removal Date	3/21/2005	3/30/2005	Remains implanted	4/22/2005	Filter removed on 5/12/2005	5/12/2005
[illegible]	Yes	Yes	Yes		Yes	Yes
Retained Segment	None	(1) Arm	Filter & (2) Detached Arms	(1) Hook	(4) Limbs	None

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Recovery Filter Detached Limbs - Patient Comparison Matrix
CONFIDENTIAL

Occurrence / Incident #	45	46	47	48	49	50
Complaint No.	47446	47613	48498	48713	48728	49055
Complaint Category	A	A	B	A	A	B
Account	Geisinger Medical Center	Tri City Medical Center East	Pitt County Memorial Hospital	Reading Hospital & Medical Center	South Jersey Healthcare	Littleton Hospital
Account Address	Danville, PA	Oceanside, CA	Greenville, NC	Reading, PA	Vineland, NJ	Denver, CO
Physician	Dr. James Elmore	Dr. Justin Goodling	Dr. Carl Cheng	Dr. Richard Duszak, Jr.	Dr. Michael Viteri	Dr. Ken Ding
Sales Rep	Larry Kebe	Chris Goodlow	Brett Hickman	Robert (Ted) Camden	Toby Capozzoli	Ben Haygood
Sample returned			No	No	No	No
Date of Implantation	11/28/2004	Nov 2004	Sept 2004	1/12/2005	Nov 2004	May-05
Date of Event	6/1/2005	6/1/2005	6/10/2005	6/14/2005	14-Jun	5/16/2005
Date reported to Bard	6/1/2005	6/1/2005	6/10/2005	6/14/2005	14-Jun	5/16/2005
Date MDR Submitted	6/29/2005	6/28/2005	7/6/2005	7/12/2005	7/7/2005	7/13/2005
Lot No.	Unknown	Unknown	Unknown	Unknown	Unknown	GFOJ1340
Filter Indication	Trauma requiring multiple orthopedic surgeries	DVT	Prophylactically after trauma	Prophylactically for gastric bypass	Trauma	DVT
Other Pt. History	Unknown	Back surgery patient	Unknown	Unknown		PE, DVT & intracranial hemorrage
Pt. Age at Time of Event	19	80	21	70	52	76
Sex	F	F	F	F	F	F
Wt Bef Height	113 lbs / 5'2"	120 lbs / 5'5"	Average	300 lbs	132 lbs / 5'6"	Average
Normal Placement?	Yes	Yes	Yes	Yes	Apex @ left renal	Unknown
Post Implant Symptoms	Asymptomatic	Dyspnea & chest pain	Unknown	Asymptomatic	Asymptomatic	None
Diagnostic Imaging	Yes	Yes	Yes	Yes	Yes	Yes
Days to Detachment	182	195	269	150	208	Unknown
Unrelated Pathology?	Yes	No	Yes	Yes	Yes	Yes
Location of limb on X-ray (initial)	1-Arm attached to caval wall	Right ventricle	Unknown	1-Arm 5mm cephalad of filter apex	1-Arm at right pulmonary vein region, 1-Arm near right atrium	Cava Wall
Location of Limb Post Removal	1-Arm pulmonary artery	Filter remains implanted, 1-arm removed via open heart surgery	1-Hook in caval wall, 1-hook & 1-arm unknown whereabouts	Pulmonary artery	Same	Filter Remains Implanted
Cava Size	11mm at implant	Unknown	Unknown	Unknown	Unknown	20mm
Patient Outcome	Asymptomatic	Stable & recovering	Unknown	Asymptomatic	Asymptomatic	Unknown
Filter Removal Date	6/1/2005	Remains implanted	6/10/2005	6/14/2005	6/14/2005	Remains Implanted
Films	Yes	Yes	No	Yes	Yes	Yes
Retained Segment	(1) Arm	Filter minus (1) Arm	(2) Hooks & (1) Arm	(1) Arm	(2) Arms	(2) Arms - Cava Wall

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Recovery Filter Detached Limbs - Patient Comparison Matrix
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Detachment / Mortality	41	42	43	44	45	46
Complaint No.	44339	50812	51422	51475	52165	52748
Complaint Category	B	B	B	A	B	B
Account	Memorial Hospital	Toronto General Hospital	St. Mary's Hospital	N. Kansas City Memorial Hospital	St Vincent Hospital	St. Vincent's Public Hospital
Account Address	Hollywood, FL	Canada	Blue Springs, MO	N. Kansas City, MO	Green Bay, WI	Australia
Physician	Unknown	Dr Rob Beecroft	Dr. Dave Burkhart	Dr. Stark	Dr. Zerrer	Dr John Urozer
Sales Rep	Patrick McDonald	Maureen Doyle	David Forbes	David Forbes	Tim Fischer	Paul Boutros
Sample received	No	No	No	No	No	No
Date of Implantation	1/3/2005	Oct-04	4/3/2005	3/26/2004	Unknown	Unknown
Date of Event	5/10/2005	5/10/2005	5/3/2005	Unknown	7/11/2005	5/21/2005
Date Reported to Bard	5/24/2005	5/27/2005	5/29/2005	7/8/2005	7/15/2005	7/10/2005
Date MDR Submitted	7/19/2005	7/6/2005	7/27/2005	7/27/2005	7/27/2005	Pending
Lot No.	Unknown	Unknown	GFOH2139	Unknown	Unknown	GFOJ0963
Filter Indication	Unknown	Unknown	DVT	PE	Unknown	Unknown
Other Pt. History	Unknown	Unknown	Post Abdominal Surgery	Small Bowel Obstruction, Degenerative Spinal Spurs	Unknown	Unknown
Pt. Age at Time of Event	41	Unknown	47	37	22	Unknown
Sex	F	Unknown	F	F	F	Unknown
Wt. and Height	Unknown	Unknown	105 lbs / Unk	160 lbs / Unk	Unknown	Unknown
Normal Placement?	Unknown	Unknown	Yes	Yes	Unknown	Unknown
Post Implant Symptoms	None	Unknown	None	None	Unknown	Unknown
Diagnostic Imaging	Unknown	Yes	Yes	Yes	Yes	Unknown
Days to Detachment	158	Unknown	30	Unknown	Unknown	Unknown
Incidental Finding?	158	Yes	Yes	Yes	Yes	Yes
Location of limb on X-ray/Initial	Unknown	Cava Wall	Unknown	Lung	8mm Lateral to Filter	Unknown
Location of Limb-Post Removal	Unknown	Cava Wall	Trapped in Filter	Lung	Filter remains implanted	Unknown
Cava Size	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Patient Outcome	Asymptomatic	Unknown	Asymptomatic	Asymptomatic	Asymptomatic	Unknown
Filter Removed/date	5/10/2005	5/10/2005	5/3/2005	Unknown	Remains Implanted	5/21/2005
Flare	No	No	Yes	Yes	No	No
Retained Segment	"2 small pieces"	None	None	(2) Arms in Lung	(1) Arm 8mm Lateral to Filter	(1) Leg remains in pt

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Recovery Filter Detached Limbs - Patient Comparison Matrix
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Detachment / Morbidity	67	68	69	70 / 3	71	72
Complaint No.	53061	53246	53377	53996	54749	55165
Complaint Category	A	B	B	A	B	B
Account	Milton S. Hershey Medical Center	Shands @ Univ of Florida Hosp	Flagstaff Medical Center	Princess Alexandra Hospital	Beth Israel Deaconess Hospital	Northern General Hospital
Account Address	Hershey, PA	Gainesville, FL	Flagstaff, AZ	Woolloongabba, Australia	Boston, MA	Sheffield, England
Physician	Dr. Frank Lynch	Dr. James Caridi	Dr. Salce	Dr. Gibbs & Dr. Harper	Dr. Ozmutl Rabkin	Dr. P. Gaines
Sales Rep	Robert Cinder	Stephen Morgan	Kevin Roslan	Mathew Lawson/Ian Frigelo	Unknown	Darren Barlow
Sample Returned	Pending	Pending	Yes	Pending	Unknown	Yes
Date of Implantation	Apr-05	May-05	7/21/2005	7/13/2005	January 2005	November 2004
Date of Event	7/26/2005	7/26/2005	7/27/2005	7/31/2005	Unknown	8/16/2005
Date Reported to Bard	7/26/2005	7/27/2005	7/28/2005	8/3/2005	8/5/2005	8/16/2005
Date MDR Submitted	Pending	Pending	8/24/2005	Pending		
Lot No.	Unknown	Unknown	GFPC1417	GHP00996	Unknown	9FOD0977
Filter Indication	Prophylactically for gastric bypass	Trauma	Prophylactically for gastric bypass	PE	Pregnancy	Unknown
Other Pt. History	Obese, family history of PE	Unknown	DVT	DVT, PE, anticoagulants use (warfarin), liver biopsy performed post filter placement	DVT & PE	Unknown
Pt. Age at Time of Event	31	Unknown	24	50's	"Young"	Unknown
Sex	F	Unknown	M	Unknown	F	Unknown
Wt (lbs)/ Height	Obese	Unknown	387 lbs	120 kg	Unknown	Unknown
Normal Placement?	Unknown	Unknown	Yes	Yes	Yes Supra renal	Yes
Post Implant Symptoms	None	Unknown	Chest pains, shortness of breath	Pt required liver biopsy	Asymptomatic	Unknown
Diagnostic Imaging	Yes	Unknown	Yes, filter had migrated	Yes	Yes	Unknown
Days to Detachment	Unknown	Unknown	6	18	Approx 210	Approx 274
Incidental Finding?	Yes	Yes	Yes, at complaint investigation	Yes	Yes, at removal attempt	Yes, at removal
Location of limb on X-ray-Initial	Retroperitoneal Cavity	Unknown	unknown - filter had migrated to tricuspid valve, fracture found post explant	Unknown	Filter migrated to renals, 1 arm detached perforated cava wall & located in liver	Unknown
Location of Limb Post Removal	Retroperitoneal Cavity	Unknown	unknown, took 4 hours to snare and remove filter, fractured leg & arm may have occurred during this time	Filter w/ clot burden migrated to heart. At autopsy, 1 Arm found embedded in rt ventricle wall	Liver	Unknown
Cava Size	Unknown	Unknown	22-23mm	24mm	< 23mm	Unknown
Patient Outcome	Asymptomatic	Asymptomatic	Asymptomatic	Death	Asymptomatic, filter tilted & unable to be removed, detached arm remains in liver	Unknown
Filter Removed date	7/29/2005	7/28/2005	7/27/2005	At autopsy, 7/31/2005	No, remains implanted	8/16/2005
Filed	No	No	Yes	Yes	Yes	Unknown
Retained Segment	(1) Limb Retroperitoneal Cavity	(1) Arm retained in pt	(1) Leg & hook, location unknown	None	Filter, (1) Arm in liver	(1) Hook, location unknown

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Recovery Filter Detached Limbs - Patient Comparison Matrix

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Detachment Frequency	73	74	75	76	77	78
Complaint No.	58454	58264	59465	59471	59931	62049
Complaint Category	A	A	B	B		A
Account	Emory University Hospital	Reading Hospital & Medical Center	Pitt County Memorial Hospital	St Luke's Medical Center	University of WA Medical Center	Sherman Hospital
Account Address	Atlanta, GA	Reading, PA	Greenville, NC	Milwaukee, WI	Seattle, WA	Elgin, IL
Physician	Dr. Elliott Chaikof	Dr. Robert Quay	Dr. Christopher Thomas	Dr. Robert Bates	Dr. Robert Andrews	Dr. Cynthia Steimle
Sales Rep	Bill Cleary	Robert (Ted) Camden	Brent Hickman	Tim Fischer	Dennis Harris	Doug Kaufman
Sample returned	Yes	No	Unknown	Unknown	Has not been returned - 10/28/05	No
Date of Implantation	Unknown	2/14/2005	12/22/2003	3/7/2005	April 2004	Unknown
Date of Event	6/18/2005	5/26/2005		9/23/2005	9/28/2005	10/19/2005
Date Reported to Bard	6/18/2005	8/26/2005	9/28/2004	9/24/2005	9/28/2005	10/19/2005
Date MDR Submitted						
Lot No.	Unknown	Unknown		Unknown	Unknown	Unknown
Filter Indication	Unknown	Recurrent PE	Unknown	DVT PE	Non-Hodgkin lymphoma	Unknown
Other Pt. History	Unknown	Anticoagulation therapy used	Unknown	Unknown	Non-Hodgkin lymphoma	Unknown
Pt. Age at Time of Event	Unknown	37	22	54	Unknown	Unknown
Sex	Unknown	F	Unknown	F	F	Unknown
Wt and Height	Unknown	220 lbs 6'	Unknown	Unknown	Unknown	Unknown
Normal Placement?	Tilted	Yes	Unknown	Yes	Unknown	Unknown
Post Implant Symptoms	Unknown	None	Unknown	Abdominal distention	Asymptomatic	Chest pain
Diagnostic Imaging	Yes	Yes	Unknown	Unknown	Yes	Yes
Days to Detachment	"Less than 1 year"	193	Unknown	200	Approx 525	Unknown
Incidental Finding?	Unknown	Yes, at removal	Unknown	Yes	Yes	No
Location of Limb on X-ray/initial	Unknown - 4 arms of filter detached	1 arm located in heart	Unknown	Cava or renal vein	2 arms in pulmonary artery	1 arm in pulmonary artery, 1 arm in atrium
Location of Limb Post Removal	Unknown	Limb not seen on echo after removal	Unknown	Filter not removed	2 arms in pulmonary artery	Unknown if filter removed, 1 arm in pulmonary artery, 1 arm in atrium
Cava Size	Unknown	Unknown	Unknown	Unknown	Unknown	Unknown
Patient Outcome	Unknown	Asymptomatic	Rep reported 2 legs & 1 hook detached from filter	Rep reported 1 leg detached from filter	Asymptomatic	Unknown - Dr requested to speak w/ Drs Venbrux & Kaufman
Filter Removal date	8/18/2005	8/28/2005	Unknown	No	Filter removed 9/30/05	Unknown
Films	No	Unknown	Unknown	Unknown	Yes	Unknown
Retained Segment	(4) Arms, (1) Hook	(1) Arm, location unknown	Unknown	Unknown	(2) Arms	(2) Arms

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Recovery Filter Migration - Patient Comparison Matrix
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Migration / Mortality	1	2	3	4	4 / 1	4 / 2	2
Complaint No.	Special Access Program Patient # 9	4101100078	5103110080	5103120008	5104020023	9942	7847
Account	Toronto General	Reading Hospital & Medical Center	Univ. Hospital of Cleveland	North Memorial Medical Center	Baptist Health South Florida	Spectrum Health	Rockford Memorial Hospital
Account City, State	Toronto, Canada	Reading, PA	Cleveland, OH	Robbinsdale, MN	Miami, FL	Grand Rapids, MI	Rockford, IL
Physician	Unknown	Peter Vile, MD	Unknown	Christopher F. Heck, MD	Dr. Powell	Dr. Banner, ME	Dr Patrizio Capasso
Sales Rep		Scot Hughes		Andy Glass	Patrick MacDonald	Dave Bourbeau	Andy Dingle
Date of Event	3/22/2000	10/17/2003	11/20/2003	11/20/2003	2/7/2004	4/13/2004 (see death cert)	4/25/2004
Date Event Reported to Bard	3/22/2000	10/17/2003	11/20/2003	12/1/2003	2/9/2004	4/14/2004	4/26/2004
Date MDR Submitted	Prior to 510(k)	Hospital 10/17/2003 Bard 11/14/2003	N/A	12/22/2003	Hospital 2/12/2004 Bard 3/9/2004	Hospital 4/13/2004 Bard 5/12/2004	Bard 5/21/2004
FDA MAUDE MDR Rpt Key	N/A	498136	N/A	503023	515707	525383	520110
Lot No.	Unknown	Unconfirmed. 07DN3845 (34 units) or 07DN3851 (35 units)	Unknown	Unknown	07DN3378, 36 units	07LN2017, 37 units	07KN2857, 41 units
Sample Returned?	No	No	No	Yes	Yes	No	No
Filter Indication	Unknown	PE	Acute PE	Massive retroperitoneal bleed from anticoagulation. Anticoagulant had to be stopped.	Pre-laparoscopic gastric bypass surgery	DVT	Unknown
Other Pt. History	Unknown	Unknown	GI Bleeding. Anticoagulants contraindicated	Left DVT, multiple PE	Morbid Obesity, Obstructive Sleep Apnea, Atrial Fibrillation, CVI Hypertension Cardiomegaly	Sub arachnoid hemorrhage	Unknown
Pt. Age at Time of Event	Unknown	Unknown	Unknown	60	34	55	Unknown
Sex	M	M	Unknown	M	M	F	M
Wt.	Unknown	Unknown	Unknown	Unknown	500 lbs	175 lbs	Unknown
Normal Placement?	Unknown	Unknown	Unknown	See "Cava Size" change below	Yes	Yes	Yes
Post Implant Symptoms	Asymptomatic	Chest Pains	Unknown	SOB, Lightheaded	Patient "passed out" and coded after a BM	None of record	Upper respiratory distress, PE
Diagnostic Imaging	Frontal and lateral digital subtraction imaging	CT	CT, Cavo gram	CT	Vena-Gram	Pre cava gram, post films	Cava gram
Days to Movement Documented	16	13	Unknown	13	0	13	91
Moved to?	T-11-T-12 disc space, cranial to level of renal vein	4cm cephalad to above the renals	Caudal shift, approx. 2cm	IVC / right atrial junction	Right Atrium	Right ventricle, per Dr. Banner, filter "ruptured the ventricle."	4cm cephalad, with filter arms in the renal vein
Cava Size	Unknown	Unknown	15-16mm	12mm at implant (hypovolemic) 24mm after rapid fluid replacement	"Just below 28mm"	"Appropriately sized" at placement, 30-35mm at time of autopsy	23mm
Clot	"Large amount of thrombus within the filter."	"Large clot in filter post implant."	Unknown	"Large amount of clot in the pulmonary arteries, right atrium, IVC, and possibly the renal veins." Large clot seen within the filter	1" x 6" clot within the filter	Per Dr. Banner's visual observation clot was formed antemortem. No histology has been done on clot.	Small amount of clot in filter
Patient Outcome	"Tolerated removal well, without developing any chest or abdominal pain."	Fine	Unknown	"Surgical thromboembolectomy of IVC, right atrium, bilateral pulmonary arteries. Post-op course unremarkable. No intraoperative complications. Procedure tolerated well."	Death on 2/7/2004	Death 4/13/2004. Reason for Death on Certificate: "Vena cava filter placed for DVT dislodged by thrombus and migrated to heart, causing cardiac rupture."	RNF removed. Greenfield filter placed via jugular route.
Filter Removed	"Filter removed per request of patient on day 16	Still implanted as of 12/1/03	Unknown	Filter removed under CP bypass, new filter successfully placed.	Filter removed at autopsy	Filter removed at autopsy	Removed on 4/26/04
Films	No	CT/Vena gram @ Dr. Kaufman	Yes	No	Yes	Digital images of films were taken by J. Harding?	Not Released to Bard

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Recovery Filter Migration - Patient Comparison Matrix
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Migration / Mortality	8 / 1	8	10	11	12 / 1	13	14
Complaint No.	9742	10623	10719	11482	12431	14543	15374
Account	Baystate Medical Center	Danbury Hospital	Rankin Memorial Hospital	Spalding Regional Hospital	St. Louis University Hospital	South Jersey Hospital	VA Medical Center
Account City, State	Springfield, MA	Danbury, CT	Oxford, MS	Griffin, GA	St. Louis MO	Bridgeton, NJ	San Francisco, CA
Physician	George Hartnell, MD	Jeet Sandhu MD	Lee V. Norris, MD	Dr. Helrich	Dr. Fnd	Dr. Pasquarelli	Dr. Sweeney, Dr. Zerr
Sales Rep	Zach House	Zach House	Jason Greer	Bill Cleary	Barb Tauscher (no rep)	Toby Capozzoli	Nikki George
Date of Event	5/8/2004	5/25/2004	6/26/2004	6/1/2004	5/30/2004	7/8/2004	7/13/2004
Date Event Reported to Bard	5/17/2004	5/28/2004	5/28/2004	6/8/2004	6/15/2004	7/12/2004	7/14/2004
Date MDR Submitted	Hospital 5/28/2004 Bard 6/14/2004	Hospital 5/28/2004 Bard 6/25/2004	Bard 6/15/04	Bard 7/7/2004	Hospital 6/15/2004 Bard 7/14/2004	Bard 8/11/2004	Bard 8/5/2004
FDA MAUDE MDR Rpt Key	530078	531130		533379	534567	538726	538201
Lot No.	GFOB1711, 44 units	Unknown	GFOD0403, 45 units	Unknown	Unknown	Unknown	Unknown
Sample Returned?	No	Yes	No	No	No	No	No
Filter Indication	History DVT, pre-vertical gastric bypass surgery	Post laparoscopic gastric bypass surgery due to GI bleeding	Pre-gastric bypass surgery	Pre-knee arthroplasty	Severe head trauma from motor vehicle accident	Pre-gastric bypass surgery	Pre-knee surgery
Other Pt. History	Morbid obesity, thrombocytopenia, smoking, asthma, right bundle BB, hypertension	Morbid obesity, history of DVT	Morbid obesity	History of DVT, PE	Cardiac drugs	Morbid obesity	Unknown
Pt. Age at Time of Event	56	Unknown	22	40	35	38	Unknown
Sex	F	M	F	F	M	F	M
Wt.	400 lbs	470 lbs	400-450 lbs	Unknown	220 lbs	Unknown	Unknown
Normal Placement?	Yes	Yes	Yes	Yes, at L2-3	Cava grams not taken. Abdominal film post implant after arms and legs open. Location not determined.	Cava not measured pre-implant. Post deployment cava gram not taken.	Yes
Post Implant Symptoms	Nausea, Vomiting, Chest tightness for several days	Abdominal pain, chest pain right arm pain	Two weeks after surgery developed nausea, much vomiting, DVT, thrombosis renal veins.	7 days post implant: Abd Pain, Swelling legs	Sudden cardiac arrest on 5/30/04	Left shoulder & abdominal pain	Asymptomatic
Diagnostic Imaging	Chest X-ray	CT	CT	KUB, Cava gram	Chest X-ray prior to death showed no filter in heart	Upper GI showed filter at L3 just after surgery. CT 14 days post surgery, filter moved to T9-10	Vena cava gram
Days to Movement Documented	37	4	21	*	10	21	60
Moved to?	Across the tricuspid valve, btw. the rt atrium and rt ventricle, Partially embedded in myocardium	Tip of filter in tricuspid valve	"Supra renal," at a cava diameter of 28-30mm	T-12	Right ventricle	T9-10	From L2 to T12
Cava Size	AP 16mm; Transverse, just under 25mm.	18mm at filter placement, 21mm after event	23mm	27mm	Not measured	Not measured	Unknown
Clot	Large amount of shaggy clot covered the filter.	"No significant in filter." Patient had PE.	"Clot within, around and on top of the filter"	7cm x 4cm clot within the filter	"Massive emboli from right femoral vein to right atrium"	Clot in the legs noted on Doppler at the same time the migration was seen on CT	Patient returned to have routine removal. Clot found in filter. Filter could not be removed
Patient Outcome	Death 5/8/2004	Fine	Pt was rapidly infused with fluids in the ER. Pt was on dialysis post migration. As of 5/27/04, there was no PE.	Pt is currently doing well. Thrombolysis is being considered due to possible caval occlusion	Death on 5/30/04	Patient was on Heparin therapy. The filter remained implanted. Could not be retrieved due to continued clot formation	Patient refused lysis therapy. Gunther Tulip was placed above the Recovery filter. Patient was fine.
Filter Removed	Filter removed at surgery	Recovery filter was removed via jugular approach thru 10mm sheath on 5/26/04. Greenfield filter placed.	Filter could not be removed due to clot on top of the filter.	Filter could not be removed due to clot. TrapEase placed via jugular approach on top of Recovery filter	At autopsy	Remained implanted	Remained implanted
Films	Pictures of chest X-ray and cava gram	CT, deployment and removal films	Photos of current placement	Film returned	Photos from autopsy, flat plate abd	No	No

Recovery Filter Migration - Patient Comparison Matrix
CONFIDENTIAL

Migration / Mortality	15	16 / 5	17	18	19 / 4	20	21
Complaint No.	14312	16467	18006	18466	18214	21298	21436
Account	Jackson Purchase Medical Center	Akron City Hospital OH	Central Dupage Hospital, IL	Riverview Medical Center, NJ	South Jersey Hospital	University Hospital of Cleveland	Providence Holy Cross
Account City, State	Mayfield, KY	Akron, OH	Winfield, IL	Red Bank, NJ	Bridgeton, NJ	Cleveland, OH	Mission Hills, CA
Physician	Dr. Alex Argote	Dr. Daniel Finell	Dr. Angelo Marinier Dr. Howard Roth	Dr. Shah / Dr. Mike Ravitch	Dr. Iqbal	Dr. Adam Blum	Dr. Greg Pavanny
Sales Rep	Matt MacIntyre	Michael Guzzo	Barbara Teuscher	Mike Stevenson	Toby Capezzoli	Michael Guzzo	Anne King
Date of Event	7/23/2004	7/24/2004	6/2/2004	8/13/2004	8/16/2004	7/4/04	9/14/2004
Date Event Reported to Bard	7/23/2004	7/29/2004	8/10/2004	8/13/2004	8/23/2004	9/2/2004	9/14/2004
Date MDR Submitted	Bard 8/23/2004	Hospital 7/29/2004 Bard 8/26/2004	Bard 8/30/2004	Bard 9/9/2004	Bard 9/21/04	Bard 10/1/2004	Bard 10/14/2004
FDA MAUDE MDR Rpt Key	540532	541353	541690	543065	545380	547544	548217
Lot No.	Unknown	GFOE2524, 43 units	Unknown	Unknown	Unknown	Unknown	Unknown
Sample Returned?	No	No	No	No	No	Yes	Yes
Filter Indication	Pre-gastric bypass surgery	PE	DVT	Prophylactic prior to a craniotomy	Prophylactic prior to gastric bypass surgery	DVT	Unknown
Other Pt. History	Morbid obesity	Achilles tendon surgery, DVT	Filter placed 2 weeks after a C-Section	Brain tumor, pt. had craniotomy 2 days post implant	Death occurred 2 weeks post op. gastric bypass surgery	History of DVT	Unknown
Pt. Age at Time of Event	42	40	35	Unknown	37	Unknown	Unknown
Sex	M	M	F	F	F	Unknown	M
Wt.	490 lbs	291 lbs	Unknown	"Heavy weight patient"	450 lbs	Unknown	> 400 lbs
Normal Placement?	Cava not measured pre-implant. Equipment produced poor visualization. No post deployment cava gram.	Placed at L1-L2, confirmed by films	Apex of filter below renal veins. Condition of legs upon deployment initially reported "twisted" later reported "unknown."	Unknown	Unknown	Yes, 1 cm below lowest renal vein	Filter did not open & immediately migrated to right pulmonary artery
Post Implant Symptoms	Unknown	Coughing, tachycardia, cyanosis, decreased O[2] saturation	Immediately migrated to the heart upon deployment	"Light back pain," PE, clot in filter	Back pain	Unknown	None
Diagnostic Imaging	C-arm used in surgery	Portable chest X-ray	Vena Cava Gram	CT	CT	Cava gram	Cava Gram
Days to Movement Documented	Day of implant	Day of implant	Day of implant	72 Days	Approx. 1 month	3 months	During implant procedure
Moved to?	Right ventricle	Root of pulmonary artery	Right ventricle	5 to 6 cm cranially, just below right atrium	Hepatic vena cava area	4 cm below right atrium	Right pulmonary artery
Cava Size	33.5mm post-implant	Calculated at 15.6mm	22mm	16mm at implant, 25-27mm at explant	Unknown	Unknown	20mm
Clot	None	4" in length distal to the filter, 1/4" diameter	None	Unknown	Left renal vein thrombosis, into the IVC	Unknown	Reported as none.
Patient Outcome	Patient transported by air to hospital in Memphis, Dr Zen percutaneously removed the filter from the heart.	Death 7/24/2004	Removal with cone unsuccessful. Filter snared to the subclavian vein. Remains implanted. A Bard Next Filter was implanted	Filter removed on 8/13/04 at another hospital	Death 8/16/2004	Unknown	TrapEase filter placed after the Recovery filter was snared & removed. Patient was fine.
Filter Removed	Yes	No	No	Yes	No	Yes, June 2004	Yes
Films	Yes (w/ Marketing)	No	Yes, CD of images	No	No	No	Yes

Recovery Filter Migration - Patient Comparison Matrix
CONFIDENTIAL

Migration / Mortality	22 / F	23	24	25 / F	26	27 / F	28
Complaint No.	21832	24244	25466	26469	26834	30641	32637
Account	Temple University Hospital	Newton Wellesley Hospital	Columbia Presbyterian Hospital	Lourdes Hospital	St. Francis Hospital	Temple University Hospital	Johnson City Medical Center
Account City, State	Philadelphia, PA	Newton, MA	New York, NY	Paducah, KY	Poughkeepsie, NY	Philadelphia, PA	Johnson City, TX
Physician	Dr. Gary Cohen ME: Dr. Lemberg	Dr. Edgar Casado, JR Dr. Neil Hayland, R	Dr. Jonathon Susman	Dr. Alex Argotte Dr. Deirdre Schneider	Dr. Louis Solis	Dr. Gary Cohen Pathologist: Dr. Lemberg	Dr. Ulises Baltazar
Sales Rep.	Hugh Magee	Bob O'Brien	Barry Broggy	MBC MacIntyre	Kristin Dorsbach	Hugh Magee	Tom Manson
Date of Event	9/9/2004	10/10/2004	10/25/2004	11/15/2004	11/15/2004	11/28/2004	12/29/2004
Date Event Reported to Bard	9/16/2004	10/13/2004	10/25/2004	11/17/2004	11/23/2004	12/4/2004	1/5/2005
Date MDR Submitted	Hospital 10/4/2004 Bard 10/14/2004	Bard 11/10/2004	Bard 11/22/2004	Bard 12/16/04	Bard 12/20/2004	Bard 12/31/04	Bard 1/20/2005
FDA MAUDE MDR Rpt Key	549336	554903		560531	561360	562812	571941
Lot No.	Unknown	GFOE1491, 43 units	GFOH0605	Unknown	Unknown	GFOH0041 43 units	Unknown
Sample Returned?	No	No	No	Yes	No	No	No
Filter Indication	Prophylactic prior to laparoscopic gastric bypass surgery	Prophylactic prior to a hysterectomy	PE	Prophylactic prior to open gastric bypass surgery	Prophylactic/Trauma	Dysphasia, brain tumor	DVT
Other Pt. History	Morbid obesity, diabetes, hypertension, obstructive sleep apnea, cardiomyopathy	History of DVT, PE, hypertension, renal failure	DVT popliteals	Venous insufficiency, leg swelling, varicosities	Multiple fractures, pneumothorax, tracheotomy, pulmonary contusion	Hypertension, peripheral vascular disease, diabetes	History of Massive PE
Pt. Age at Time of Event	45	48	Unknown	33	44	65	49
Sex	F	F	M	F	M	M	M
Wt.	345 lbs	Unknown	Unknown	Morbidly obese	Unknown	256 lbs	Unknown
Normal Placement?	Yes	Yes, below renals	Yes, below renals	Yes	Yes, below the renals	Yes, at L2, just at renal vein	Unknown
Post Implant Symptoms	Pt had complications of GB procedure (leak), developed hematoma & clot at access site	Abdominal pains, shortness of breath	None	None	Back pain	Seizure	None
Diagnostic Imaging	CT	Cava grams	Cava gram	None	Cava gram	No	CT
Days to Movement Documented	25	5	9	19	28	11	28
Moved to?	Right ventricle	7-12	Tip in right atrium, legs in cava	Right Ventricle	Supra-renal	Ventricle	2cm cephalad. Filter arms above renals, legs below renals
Cava Size	22mm	20mm	Not measured at implant	18mm	20mm	17mm at implant, 26mm several days later	Predeployment 23.4mm, 31mm on 1/12/05
Clot	Picture showed clot filled the filter 4 hrs & loop tail	"Filter was full of clot"	Unknown	Small amount in the filter, 1 cm clot 20cm in pulmonary vasculature	Large amount of clot seen in the IVC below the renals	Unknown	10cm in filter
Patient Outcome	Patient experienced a PE and expired on 9/9/2004	Transferred to New England Medical Center for assessment. Filter removal attempt unsuccessful	Unknown	Death on 11/15/04	Fine	Death on 11/29/2004	Fine
Filter Removed	Yes	No	Yes, 10/25/04	Yes	Yes, 11/22/04	Unknown/autopsy performed	Remains implanted
Titres	No	No	No	No	No	No	Yes

Recovery Filter Migration - Patient Comparison Matrix
CONFIDENTIAL

Migration / Mortality	29	30	31	32	33	34	35
Complaint No.	33380	33382	33083	34400	40584	40599	43942
Account	Berkshire Medical Center	Overlake Hospital	Lake Forest Hospital	St. Rita's Medical Center	New Hanover Memorial Hospital	Providence Alaska Medical Center	Providence St. Margaret Health Center
Account City, State	Pittsfield, MA	Bellevue, WA	Lake Forest, IL	Lima, OH	Wilmington, NC	Anchorage, AK	Kansas City, KS
Physician	Dr Kevin McConnell	Dr. Pierre-Jerome Dr. Mark Flenker	Dr. David Kozloff	Dr. Pavan Panudoti	Dr. Clint Atkinson	Dr. Coyle / Drs. Meurer & Inampudi	Dr. Craig McClure
Sales Rep	Zach Haude	Kathleen Spalgo	Doug Kaufman	Jennifer Keener	Brett Hickman	Kathleen Spalgo	Dave Forbes
Date of Event	1/14/2004	1/7/2005	1/17/2005	1/20/2005	3/17/2005	3/29/2005	4/17/2005
Date Event Reported to Bard	1/14/2004	1/14/2005	1/18/2005	1/20/2005	3/21/2005	3/29/2005	4/28/2005
Date MDR Submitted	Bard 1/31/2005	Bard 2/6/05	Bard 1/31/05	Bard 2/8/05	Bard 4/15/05	Bard 4/7/05	Bard 5/23/05
FDA MAUDE MDR Rpt Key	574154	574895	569583	572279			
Lot No.	GTHH0263, 27 units	Unknown	GFOF0598, 31 units	GFDE1579, 34 units	Unknown	GFDG4090 37 units	Unknown
Sample Returned?	No	No	No	Yes	No	Yes	No
Filter Indication	Bilateral pulmonary embolism	KVA trauma, DVT	Recurrent DVT in spite of anticoagulation	Recurrent PE, anticoagulants were not effective alone.	Unknown	Unknown	Contra-indication for heparin due to coronary bypass surgery
Other Pt. History	Unknown	Developed caval thrombosis, bilateral ilio-femoral DVT 27 days after filter placement.	Unknown	Unknown	Unknown	Unknown	Open heart surgery, osteomyelitis of sternum
Pt. Age at Time of Event	57	Unknown	72	45	Unknown	Unknown	58
Sex	M	M	F	F	M	Unknown	M
Wt.	Unknown	Unknown	230 lbs	"Average build"	Unknown	Unknown	Unknown
Normal Placement?	Yes, at L1-L2	No, filter had to be placed at L3 low left renal vein	Yes	Yes	Unknown	Unknown	Yes
Post Implant Symptoms	None	Thrombosis of left renal vein	Pain, leg swelling	Chest pain	Unknown	Unknown	Unknown
Diagnostic Imaging	Cava gram	CT	CT	CT	Cava gram	Unknown	Yes
Days to Movement Documented	92	27	51	128	180	73	31
Moved to?	4cm to T12	5cm from L3 to L1, above the renals	5cm, above right renal, just below hepatic vein	Right atrium	Filter to in right atrium	Caught in caval stenosis, distal to right atrium	Heart
Cava Size	Unknown	"Less than 3cm"	18mm	14.7mm at implant, 28.7mm when it migrated.	Unknown	Unknown	23mm
Clot	None	Filter and cava clot burdened	"Small amount"	4.7 x 2.2 x 2cm	Unknown	Unknown	Present in pulmonary artery (saddle embolus)
Patient Outcome	Fine	Placed on Heparin, Patient was fine	Fine	Pt had open heart surgery to remove filter. Birds Nest filter placed percutaneously. Patient was fine.	Pt had surgery to remove filter, patient was fine	Filter successfully removed, patient was fine.	Filter successfully removed, patient was fine.
Filter Removed	Removal attempted, detached leg found perforating cava wall. Leg was removed, filter remained implanted.	No	Unable to remove as filter was tilted	Removed on 1/21/05, 1 hook detached	Yes	Yes	Yes
Films	No	Yes	No	No	No	Unknown	Yes

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Recovery Filter Migration - Patient Comparison Matrix
CONFIDENTIAL

Migration / Mortality	34	37	34	39 / 10	40 / 11	41 / 12	47
Complaint No.	44811	45719	45713	46117	46784	44066	47650
Account	Parkland Memorial Hospital	Sentara Norfolk General Hospital	Sentara Norfolk General Hospital	Norton Audubon Hospital	Lovelace Medical Center	Cape Girardeau Surgical Clinic	Washington Hospital Center
Account City, State	Dallas, TX	Norfolk, VA	Norfolk, VA	Louisville, KY	Albuquerque, NM	Cape Girardeau, MO	Washington DC
Physician	Dr. Jorge Lopez	Tech: Joseph Cuco	Dr. Martin A. Fogel	Dr. Clifton Tatum, Dr Jorge Rodrigues	Dr. Robert Mats, Dr. Luis Centeno	Dr. Colleen Johnson	Dr. Richard Gray
Sales Rep	Brooke Gillette	John Pleshal	John Pleshal	Michael Crab	Chris Hickok	Tim Helfrich	Kevin Jackson
Date of Event							
Date Event Reported to Bard	5/1/2005	5/18/2005	5/16/2005	5/12/2005	5/16/2005	5/18/2005	5/31/2005
Date MDR Submitted	Bard 5/31/05		5/18/2005	5/14/2005	5/16/2005	5/19/2005	6/8/2005
FDA MAUDE MDR Rpt Key							
Lot No.	Unknown	Unknown	Unknown	Unknown	CFPC5902	CFOL2711, 33 units	Unknown
Sample Returned?	No	No	No	No	No	No	No
Filter Indication	Unknown	Neuro-surgical & craniotomy at	Trauma, DVT	Unknown	Metastatic Cancer, DVT	Prophylactic placement for laparoscopic gastric bypass surgery	Bariatric procedure
Other Pt. History	Unknown	DVT	Contraindication for anticoagulation	Anticoagulants for 30 days prior to surgery	Unknown	Morbidly obese, BMI 66	Anticoagulants not used due to religious reasons
Pt. Age at Time of Event	Unknown	30	46	28	52	28	Unknown
Sex	Unknown	M	M	F	M	F	F
Wt.	Overweight, not morbidly obese	Unknown	220 lbs	675 lbs	Unknown	371 lbs	400 lbs
Normal Placement?	Yes	Femoral	Yes	Yes	Unknown	Yes	Yes
Post Implant Symptoms	Unknown	Unknown	Right upper quadrant abdominal pain, back pain	Pt complained of chest pains, and expired	Shortness of breath	Shortness of breath, chest pains	None
Diagnostic Imaging	CT	Unknown	CT	Unknown	Unknown	Yes	Yes
Days to Movement Documented	Unknown	Unknown	353	21	10	22	106
Moved to?	Moved 3cm into renals	3cm into hepatic IVC	5cm into hepatic IVC	Right atrium	Heart	Right atrium	2-3 cm Caudally
Cava Size	Unknown	Unknown	Unknown	18mm at placement	Unknown	"Normal"	Unknown
Clot	Unknown	"Massively clot burdened"	Unknown	"Massive clot burden," saddle embolus confirmed at autopsy	Unknown	Clot noted in right atrium	None
Patient Outcome	Fine	Filter remains implanted	Unknown	Death on 5/12/2005	Death on 5/16/2005	Death on 5/18/05	Asymptomatic, remains implanted
Filter Removed	Filter removed on 5/17/2005, 4 detached limbs remain in patient.	No	Yes	At autopsy	Unknown	Unknown	No
Perfs	Unknown	Unknown	Unknown	Unknown	Unknown	Yes	Yes

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Recovery Filter Migration - Patient Comparison Matrix
CONFIDENTIAL

Migration / Mortality	43	44	44	46	47	48	49 / 13
Complaint No.	47880	49027	49088	49667	48324	43377	48998
Account	St Mary's Hospital	Florida Hospital	St Joseph's Hospital	Samaritan Healthcare	Hartford Hospital	Flagstaff Medical Center	Princess Alexandra Hospital
Account City, State	Richmond, VA	Orlando, FL	Phoenix, AZ	Phoenix, AZ	Hartford, CT	Flagstaff, AZ	Woolloongabba, Australia
Physician	Dr. Niel Hutcher	Dr. Ostmayer	Dr. Lensuze	Dr. Grauer	Dr. Dan Vanbutic	Dr. Setox	Dr. Gibbs & Dr. Harper
Sales Rep	John Flashel	Bruce LaBreche	Kevin Haslam	Kevin Haslam	Zack Hourde	Kevin Haslam	Mathew Lawson/Ian Ingano
Date of Event	6/1/2005	6/15/2005	June 2005	June 2005	6/16/2005	7/27/2005	7/01/2005
Date Event Reported to Bard	6/2/2005	6/16/2005	6/16/2005	6/16/2005	6/17/2005	7/28/2005	8/3/2005
Date MDR Submitted	Bard 6/21/2005 Hospital 6/8/2005						
FDA MAUDE MDR Rpt Key							
Lot No.	GFPO0078, 34 units	Unknown	Unknown	GFPD0617	GFDJ0093	GFPC1417, 38 units	GFPC0985
Sample Returned?	No	No	Ny	No	No	Yes	Unknown
Filter Indication	Prophylactic placement for gastric bypass surgery	Unknown	Trauma	Craniotomy	Unknown	Prophylactic placement 1 day prior to gastric bypass surgery, DVT, & PE	PE
Other Pt. History	Anticoagulants were used	DVT, PE	Unknown	Glioblastoma multiforme DVT, multiple PE	Unknown	Morbid obesity	DVT, PE, anticoagulants used (warfarin), liver biopsy performed post filter placement
Pt. Age at Time of Event	33	31	Unknown	Unknown	Unknown	24	50's
Sex	F	F	Unknown	R	Unknown	M	Unknown
Wt.	500 lbs	110 lbs	Unknown	200 lbs	Unknown	387 lbs	265 lbs
Normal Placement?	Yes	Yes, however Dr placed at lowest renal. Rep had reservations Dr on placement further below renals.	Unknown	Yes	Yes	Yes	Yes
Postimplant Symptoms	Chest pain, shortness of breath	None	Unknown	2 syncopal episodes	Unknown	Chest pain, shortness of breath	Unknown
Diagnostic Imaging	Yes	Yes	Unknown	CT	CT	Yes	Yes
Days to Movement Documented	22	83	Approx 80	"few months"	143	4	18
Moved to?	Below right atrium	2arms in renals, filter tilted	Supra renal vena cava	Rt atrium, rt atrial-internal vena cava	Hepatic/right atrium junction	Tricuspid valve/ ventricle/ atrium region	Lodged against tricuspid valve, 1 detached arm embedded in rt ventricle wall
Cava Size	Unknown	24.5mm	Unknown	Unknown	Unknown	22-23mm	24mm
Clot	Filter was "heavily burdened," residual clot remained in heart after snare removal	Filter removed with clot, clot also found in iliac	Unknown	Clot burdened filter	Unknown	Clot & tissue found at removal	"Ping-pong ball" sized clot
Patient Outcome	Pt under observation for 1 week then released, asymptomatic	Asymptomatic	Asymptomatic	Open heart surgery to remove filter	Unknown	Asymptomatic	Death, July 31, 2005
Filter Removed	Yes	Yes, with clot	Yes	Yes with multiple clot	Yes	Yes, with Recovery Cone	Yes, with detached limb noted
Films	Yes	No	No	Unknown	Unknown	Yes	Yes

Recovery Filter Migration - Patient Comparison Matrix
CONFIDENTIAL

Migration / Mortality	50	51	52	53	54	55 / 14	56
Complaint No.	54442	54401	54749	54293	67647	59421	65478
Account	Mountainside Hospital	Rose Medical Center	Beth Israel Deaconess Hospital	St Joseph Mercy Health System	University of Chicago Hospital	Sentara Norfolk General Hospital	Reading Hospital & Medical Center
Account City, State	Montclair, NJ	Denver, CO	Boston, MA	Ypsilanti, MI	Chicago, IL	Norfolk, VA	Wyomissing, PA
Physician	Dr. Holmes	Dr. Julie Park	Dr. Darrell Rabkin	Dr. David Kaston	Dr. Brian Funaki	Dr. Richard DeMasi, Dr. Greg Barber	Dr. Robert Guay
Sales Rep	Robert Ferrara	Ben Haygood	Paul Benevers	Dave Bourbeau	Tim Ridinger	John Plashal	Tex Camden
Date of Event	8/9/2005	8/8/2005	8/5/2005	8/16/2005	9/6/2005	9/21/2005	10/4/2005
Date Event Reported to Bard	8/9/2005	8/10/2005	8/5/2005	8/15/2005	9/9/2005	9/25/2005	10/4/2005
Date MDR Submitted							
FDA MAUDE MDR Rpt Key							
Lot No.	Unknown	GFOL2725	Unknown	Unknown	Unknown	Unknown	Unknown
Sample Returned?	No	Yes	No, remains implanted	No	No	No	No
Filter Indication	Prophylactic placement prior to gastric bypass surgery	Prophylactic placement for intercranial bleeding & stroke	Pregnancy	Lower extremity DVT	Shunt placed*	Prophylactic placement prior to gastric bypass procedure	Prophylactic placement prior to gastric bypass procedure
Other Pt. History	Morbid obesity	Unknown	DVT & PE	Contraindication for anticoagulation	DVT, recurrent PE	Morbid obesity	Morbid obesity
Pt. Age at Time of Event	Unknown	Unknown	"Young"	67	44	67	52
Sex	Unknown	M	F	M	M	F	M
Wt.	Morbidly obese	168 lbs / 5'11" Tall	Unknown		Non-obese	350 lbs	< 440 lbs
Normal Placement?	No	Yes	Yes, Supra renal	Yes	Yes, CT in mid 2005 showed filter still in planned implant location	Unknown	Yes
Post Implant Symptoms	Filter immediately migrated to rt atrium upon deployment	Unknown	Asymptomatic	Shortness of breath	Chest pain	Leg swelling, shortness of breath small bilateral PE, & pericardial effusion unrelated to filter	None
Diagnostic Imaging	Yes	CT revealed 4cm filter movement	Yes	CT showed massive PE, clot burdened filter migration, one leg perforated cava wall, & tilted filter	Yes, CT in mid 2005 showed filter still in planned implant location	CT confirmed filter in rt atrium	Yes
Days to Movement Documented	0	20	Approx 210	Approx 30	278	≤ 21	100
Moved to?	Rt atrium	Migrated to distal heart area w/ several legs puncturing the VC	Migrated to renals, 1 detached arm perforated cava wall & in liver, 1 detached leg near spine, 1 detached leg near aorta	> 2 cm	Migrated to tricuspid valve with bilateral PE	Right atrium	2-3 cm
Caval Size	23mm	< 28mm; 20-22mm	less than 23mm	Unknown	19.8mm	not measured at implant, 23-31mm at migration	18mm
Clot	None	Unknown	Unknown	Filter heavily clot burdened	Unknown	3 cm "golf ball sized"	None
Patient Outcome	Asymptomatic	Filter removed & new filter placement not needed	Asymptomatic, filter tilted and not able to be removed, detached arm remains in liver	Greenfield filter placed superior to RNF, patient asymptomatic	Asymptomatic, no indication of damage to heart	[illegible] to filter, pt arrested during pulsed spray to break up clot. CPR performed & pt stabilized. Rt atrium was opened & pt arrested again, resulted in death, 9/23/2005	Asymptomatic
Filter Removed	Surgically removed after failed removal with Recovery Cone	Yes	No, remains implanted	No	Surgical removal via median sternotomy	Not removed, autopsy not performed	Yes
Films	No	Yes	Yes	Yes	Yes	No	Yes

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11/1/2005

Recovery Filter Migration - Patient Comparison Matrix

CONFIDENTIAL

Migration / Mortality	57	68 / 16	69
Complaint #	65439	61841	62171
Account	University of Mississippi Med Ctr	St Agnes Healthcare	Columbia Hospital
Account City, State	Jackson, MS	Baltimore, MD	Milwaukee, WI
Physician	Dr. Otis Glass	Dr. Nicholas Zinnis	Dr. Tomashek & Dr. Mairquard
Sales Rep	Nicole Alga	Lee Gleason	Tim Fischer
Date of Event	October 2005	10/18/2005	10/20/2005
Date Event Reported to Bard	10/4/2005	10/19/2005	10/20/2005
Date MDR Submitted			
FDA MAUDE MDR Report #			
Lot No.	Unknown	Unknown	Unknown
Sample Returned?	No	No	No, remains implanted
Filter Indication	Unknown	CI Blockage due to Heparin therapy for DVT & clotted cardiomyopathy	Prophylaxis for fort surgery
Other PL History	Unknown	Unknown	Morbid obesity
PL Age at Time of Event	35	60	59
Sex	M	M	F
Wt	Unknown	Non-charted	300
Normal Placement?	Unknown	Yes	Unknown
Post Implant Symptoms	Unknown	Shortness of breath, chest & pelvic pain	Clots became promboses & kidneys shut down
Diagnostic Imaging	Unknown	CT Scan	Unknown
Days to Movement Documented	> 21	16	Approx 30
Moved to?	Right atrium	Lodged between rachium & ventricle of heart in bifurcation/valve	Above renals
Cava Size	Unknown	Unknown	Unknown
Clot	None at removal	Unknown	Heavy clot burden
Patient Outcome	Asymptomatic	Death on 10/19/2005	Asymptomatic, clots upon & kidneys once again producing urine
Filter Removed	Yes	Unknown, unknown if attempted	Remains implanted
Fibrin	No	Unknown	Unknown

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EXHIBIT 43

Health Hazard Evaluation

DATE: July 9, 2004

TO: Doug Uelmen, BPV QA

FROM: David Ciavarella, M.D.

RE: Limb Fractures of Recovery® Filter

Summary: Seventeen reports of Recovery filter fracture have been received (rate of 0.17%). In 6 cases, fragments migrated to the heart or lung (rate of 0.06%), and in one of these cases, the patient developed serious cardiac symptoms requiring open heart surgery to correct. No other injuries have been reported. A literature review reveals that filter fracture is a known complication of IVC filters, with reported rates in the range of 0.05 to 10%. Recovery filter fracture rates exceed the rates reported by other manufacturers in the MAUDE database, but direct comparison of these filters to Recovery is not possible due to the imprecise & subjective nature of the MAUDE database and the unique retrievability features of the Recovery system.

Conclusion: The Frequency category for serious injury (Critical Severity rating) is Remote (approximately 0.06%). The Hazard Risk Matrix Number is 10. The Frequency category for non-serious injury (Marginal Severity rating) is Occasional (approximately 0.17%). The Hazard Risk matrix Number is 11.

Description of the Problem: From January 2002 through June 2004, there have been 17 reports of limb fractures of the Recovery Filter, part of the Recovery Filter System for use in the Vena Cava. During this period, approximately 12,700 units have been sold. Assuming about 2500 units on the shelf (based on 2.5 units each for 992 accounts), about 10,200 Recovery filters have been implanted.

In 1 of the 17 reports, the filter was "slightly angulated" upon deployment. Placement was reported as normal in 6 cases and no information about the placement of the filter is available in the remaining 10 cases. The indications for filter placement were prophylactic in 7 cases, unknown in 5 cases, and on-label in 5 cases. The fractured limbs were discovered at the time of scheduled filter retrieval in 15/17 cases (88%). None of these 15 patients had symptoms related to their fractured filter or retained filter fragments, either before or after retrieval. Two of the 17 patients (12%) presented with symptoms that prompted evaluation of the filter. One patient underwent a CT scan for a complaint of chest pain. The filter arm was noted in the R ventricle, but the patient's physicians were unable to state that the filter fragment (which was left in the ventricle) was the cause of the chest pain. In the second symptomatic case, the patient presented with sudden shortness of breath and syncope. Hemopericardium and cardiac arrhythmia were diagnosed. A detached filter arm was noted in the ventricular wall, and it was removed during open heart surgery.

In 6 of the cases, hooks (leg ends) were detached; none of them were retrieved, i.e., they all remain in the patient, presumably bound to the wall of the inferior vena cava (IVC). A total of 20 arm fragments were reported in 14 cases (3 patients had detached hooks and arms). Eleven of 20 arms (55%) remain in the patient, and in 6 patients (30%), the detached arms migrated to the heart or lungs. Two detached arms have not been located; 1 of these is thought to remain *in vivo*. Information concerning the size of the retained filter fragments is available in only 4 cases; the hooks range in size from 3.6 to 4.1 mm, while the size of the only measured arm fragment was 21.6 mm. The time range for discovery of the fracture after implantation is 30 to 237 days, with a median time of 95 days.

The root cause of the fractures has not been determined, and an in vitro test method to simulate the in vivo environment does not yet exist. The arm fractures have occurred in a consistent location at the top of the filter.

The Actual Occurrence of Injuries: Six cases had associated migration of a fragment to the heart or lung (in 1 case, the location of the fragment in vivo remains unknown). Serious injury has occurred in only 1 patient, the one in which open heart surgery was required to remove a filter arm that had pierced the ventricle and given rise to syncope presumed due to an arrthymia. Another patient presented with chest pain of undetermined origin. The remaining cases have not reported symptoms or associated injury up to the time of this HHE.

Human Exposure to the Problem: As noted above, about 10,000 Recovery filters have been placed.

General Consequences: Most cases of filter fracture, both those reported here and those in the literature, are without consequence.[1,2] As seen in one case associated with the Recovery filter, migration of filter fragments to the heart or lung has the potential to cause tissue erosion and associated cardiac arrhythmias and tamponade, pulmonary hemorrhage and airway damage. Any patient with a patent foramen ovale is at additional risk of paradoxical embolization of the filter fragments, with the possibility of stroke or other end organ damage.

Population Exposed to the Risk: All patients in whom a vena cava filter is placed are at risk for this complication.

Mitigating/Predisposing Factors in the Population at Risk: Unknown. It is theoretically possible that hemodynamic stresses predisposing to fracture might result from mis-alignment of the filter in the IVC. However, the reports do not include evidence or even suspicion of mis-alignment.

Nature & Seriousness of the Risk: The effect of filter fracture is no discernible effect in most cases. Serious injury may occur in a minority of cases, and sudden death is a theoretical possibility. In the MAUDE database, 25 cases of fractured IVC filters from manufacturers other than CR Bard are listed for the period of 2000 through 1Q2004. No deaths were reported, and serious injury was reported in 3 cases (1 case: fragment pierced the kidney; 1 case – fragments pierced the spine and aorta; 1 case – fragment lodged in the liver).

Likelihood of Occurrence of the Problem: No well-controlled trial exists to answer this question definitively for any filter. Review of the literature reveals a risk of filter fracture in the range of a few percent. Kinney quotes a fracture rate of 1%,[1] while Streiff quotes rates from published studies of 0%, 1.7%, 2.8% and 14.1%, respectively, for the Greenfield, Vena Tech, Bird's nest and SNF filters.[2] Greenfield and Proctor[3], Ferris et al.,[4] and McCowan et al.[5] quote rates of fracture of 0.05%, 2%, and 10%, respectively.

The MAUDE database contains 25 reports of filter fracture from 4 manufacturers other than CR Bard in the period of 2000 through 1Q2004. Market information permits an estimate of about 425,000 IVC filters implanted from these 4 manufacturers during this time. Symptoms and serious injury were reported in 3 cases each, and death in no cases. The *MDR rates* of complications for other manufacturers filter are therefore:

Overall fracture rate:	25/425,000, 0.006% or 1 per 17,000 filters
Symptomatic rate:	3/425,000, 0.0007% or 1 per 141,667 filters
Serious injury rate:	3/425,000, 0.0007% or 1 per 141,667 filters
Death rate:	0%

These MDR reported fractures occurred in permanent filters. There have been no reports of fracture in 2 retrievable filters, the Cook Tulip™ and Cordis Optease™, with an estimated 4,000 and 1,500 filters implanted, respectively.

Reported fracture rate data for the Recovery filter are as follows:

Overall fracture rate:	17/10,200, 0.17% or 1 per 600 filters
Migration to chest:	6(7)*/10,200, 0.06% (0.07%), or 1 in 1,700 (1457)
Symptomatic rate:	2/10,200, 0.02% or 1 per 5,100 filters
Serious injury rate:	1/10,200, 0.01% or 1 per 10,200 filters
Death rate:	0%

* 6 fragments are known to have gone to heart or lung; the in vivo location of 1 fragment is unknown

These MDR rates are not directly comparable to the observed rates with the Recovery filter for several reasons. First, the MAUDE database reflects only those events reported by the manufacturers, who can differ widely in their interpretation of reporting requirements. Thus different manufacturers may not classify all episodes of fracture as MDR reportable. Perhaps more importantly, however, the Recovery filter is a retrievable filter, and the fracture event was discovered on account of the retrieval procedure in 88% of cases (15/17) at a median time of 95 days after implantation. Fractures in permanent filters are discovered only incidentally, as routine monitoring of implanted filters is not common practice. This could lead to an underreporting bias for the permanent filters. Although no fractures have been reported to date for the other retrievable filters, the estimated number implanted is low. In addition, these filters are retrieved relatively soon after implantation. The mean (range) days before retrieval for Optease and Tulip are 16 (3-48 days) and 11(2-20),[6,7] respectively, timeframes in which no Recovery filter fractures were reported.

Likelihood of Harm if the Problem Occurs: Filter fragments which remain attached to the IVC, or migrate to a similar location, are theoretically capable of causing tissue erosion and foreign body reactions of various kinds. However, as observed in these cases and from literature review, they are generally of little clinical consequence. By analogy, penetration of the IVC wall by intact filters in not infrequent (reported to occur from 0-41% of cases); however, serious injury is very rare. Migration of metal fragments to the heart or lung presents the possibility of cardiac or pulmonary injury with serious clinical consequences. In patients with a patent foramen ovale, left sided embolism is possible, with attendant risk of stroke or other end organ damage. The likelihood of harm caused by fracture of the Recovery filter can be assessed as follows:

Likelihood of migration to heart or lung:	6(7)*/10,200, 0.06% (0.07%), or 1 in 1,700 (1457)
Likelihood of serious injury:	1/10,200, 0.01% or 1 in 10,200

* 6 fragments are known to have gone to heart or lung; the in vivo location of 1 fragment is unknown

Is the Product Essential to Health: Yes. It is particularly important in patients with a limited time frame of high risk of thromboembolism for whom anticoagulation if contraindicated or ineffective (about 20% or more of patients).

Is there an Alternative Available: Yes. Alternative IVC filters exist, but the ability to retrieve the Recovery filter in patients with transient risk of venous thromboembolism makes it an important treatment option for many patients.

Must the Problem Device be Removed or Corrected Surgically: Yes, in some cases.

Is the Problem Expected & Within an Acceptable Statistical Range: See answers above for Likelihood of Occurrence and Likelihood of Harm. Statistical analysis of rates of fracture for Recovery versus

other filters is not directly possible, due to lack of comparable datasets. Filter fracture and consequent injury rates for Recovery are well below those reported in the literature (with the one exception of reference 3), but substantially above those reported as MDRs by other filter manufacturers. For the reasons noted above, however – primarily retrievability features – data allowing a direct comparison of the Recovery filter with any other IVC filter are not available.

Can the Problem be Corrected in the Field: Percutaneous retrieval of the filter fragments is sometimes possible, leading to correction/mitigation of the hazard. However, when the fragment is in a difficult location, retrieval may be impossible or contraindicated.

Is the Problem or Health Hazard Obvious to the User: As mentioned above, filter fracture is a known complication of IVC filter placement, and information concerning this hazard has been placed in the Recovery IFU. However, there is no way to predict which patients will develop this complication. More frequent monitoring of the filter once placed may facilitate discovery of abnormal placement (a *possible* but not proven predisposing factor for fracture) or indeed of a fractured filter, but could not prevent all potential adverse events.

Can the Product Continue to be Used with Proper Warnings: Yes.

Is the Device Used Only by Specially Trained Health Care Professionals: Yes.

References:

1. Kinney TB: Update on inferior vena cava filters. *J Vasc Interv Radiol* 2003; 14:425-440.
2. Streiff MB: Vena caval filters: a comprehensive review. *Blood* 2000; 95:3669-3677.
3. Greenfield LJ & Proctor MC: Filter complications and their management. *Semin Vasc Surg* 2000; 13:213-216.
4. Ferris EJ, McCowan TC, Carver DK, McFarland DR: Percutaneous inferior vena caval filters: follow-up of seven designs in 320 patients. *Radiology* 1993; 188:614-615.
5. McCowan TC, Ferris, Carver DK, Molpus WM: Complications of the nitinol vena caval filter. *J Vasc Interv Radiol* 1992; 3:401-408.
6. Instructions for Use, Cordis OptEase™Vena Cava Filter.
7. Instructions for Use, Cook Günther Tulip™ Vena Cava Filter

EXHIBIT 46

Updated Health Hazard Evaluation

DATE: June 30, 2004

TO: Doug Uelmen, BPV QA

FROM: David Ciavarella, M.D.

RE: Migration of Recovery® Filter

N.B.: This HHE is an update to two prior HHEs performed for the same hazard by Dr. John Lehmann. These HHEs were submitted as part of Remedial Action Plans on March 10, 2004 and April 27, 2004. This update includes information from all reported cases of migration of the Recovery filter through June 29, 2004.

Summary: Migration of a thrombus-encased Recovery inferior vena cava (IVC) filter has been reported in 10 patients. In two additional cases, filter migration without associated thrombus was probably the result of mis-deployment, which, in one of these cases, led to iatrogenic filter displacement to the heart. The root cause of the thrombus-associated migration events is judged to be thrombus-induced pressure increase in the IVC, leading to acute IVC expansion beyond the design limits of the filter. The overall rate of this complication of placement of Recovery filters is comparable to the rate reported by other IVC filter manufacturers.

Conclusion: The Severity category for the risk of thrombus-associated filter migration is Catastrophic, and the Frequency category is Remote (approximately 0.05%). The Hazard Risk Matrix Number is 8.

Description of the Problem: There have been 12 reports of migration of the Recovery Filter, part of the Recovery Filter System for use in the Vena Cava. Filter migration has been defined in the literature (and for the purposes of this HHE) as movement of the filter of > 2 cm from the site of deployment. A further important distinction in the definition of migration is whether the filter alone has moved or has moved as a component of a thromboembolus. In the first case, a hazard is created by the unintended movement of the filter. In the second case, the "malfunction" is best understood as a limitation of the ability of the device to carry out its intended function. These limitations are spelled out in the literature and in the IFU.

In 2 of the 12 reports, migration was of the filter alone. One case involved minimal cephalad migration and tilting, leading to the physician's decision to retrieve the filter percutaneously (as per IFU). The second case was iatrogenic, caused by the physician's technically incorrect manipulation of a filter that had deployed with crossed legs. This mechanically displaced filter migrated to the heart requiring open cardiac surgery to remove it.

The remaining 10 cases involved migration of filter encased in large thrombi. In these cases, no problems of a technical nature were reported during the placement procedure, that is, the filters were properly deployed into vena cavae of appropriate size (≤ 28 mm). Of these remaining 10 cases, 4 involved migration within the inferior vena cava (3-4 cm cephalad movement) and 6 involved migration to the heart, typically to the R atrium/tricuspid valve. Of the 6 events involving thrombi-encased filters that migrated to the heart, 4 were associated with patient death. No cases of spontaneous migration to the heart unassociated with large thrombus have been reported.

The root cause of the migration event in these 10 cases is judged to be dislodgment of the filter due to the presence of a large thrombus. The exact mechanism of the dislodgment is unknown, but is presumed due to an acute increase in intracaval pressure (caudal to the filter) with resulting expansion of the IVC beyond the design limits of the filter. It is further presumed that the large thrombus caught in the filter was the primary contributor to the acute increase in intracaval pressure. In some cases, pathological examination revealed evidence suggesting that thrombus growth may have occurred at the site of its capture by filter. .

The Actual Occurrence of Injuries:

Information about injuries to the 4 patients with migration confined to the IVC is provided as follows:

1. A patient with a myocardial infarction with a 3-4 cm cephalad migration of the filter had it removed along with the thrombus on day 16 after insertion without difficulty.
2. A patient with (presumed) idiopathic venous thromboembolic disease with a 4 cm cephalad migration was not subjected to a retrieval procedure due to the large clot. No further information is available.
3. A patient with morbid obesity underwent placement of the Recovery filter 2 weeks prior to bariatric surgery. She developed nausea and vomiting 2 weeks after surgery and was rapidly rehydrated in the hospital. DVT developed with lower extremity edema and renal failure. CT scan revealed that the filter had migrated cephalad to the renal veins, which were thrombosed. At last follow-up, the patient was undergoing dialysis for renal vein thrombosis. There were no imminent plans to retrieve the Recovery filter.
4. A patient with a history of DVT underwent Recovery filter placement before knee surgery. Abdominal pain and lower extremity edema developed 7 days later. The Recovery filter had migrated minimally to the level of T12, associated with a 7 cm x 4 cm thrombus encasing and deforming the filter. A TrapEase IVC filter was placed above the Recovery filter using a jugular vein approach. Thrombolytic therapy for IVC occlusion was being considered at last follow-up.

Information about the 6 patients in whom the thrombi-encased filter migrated to the heart is provided as follows. Two (2) patients survived the migration event without further complication.

1. A patient with (presumed) idiopathic venous thromboembolism developed significant bleeding due to anticoagulation therapy. This was stopped, and a Recovery filter placed. The patient subsequently developed SOB and lightheadedness. On investigation, extensive thrombus was noted in the pulmonary artery, R atrium and IVC. The thrombus encased filter was in the R atrium. Successful surgical embolectomy with filter removal was performed, and the patient recovered without further complication.
2. A bariatric surgery patient developed a major GI bleed associated with coumadin therapy. Coumadin was stopped and a Recovery filter was placed without difficulty. Five days later the patient developed chest and abdominal pain. Investigation revealed a large thrombus encasing the filter across the tricuspid valve. It was removed percutaneously without trouble, and a Greenfield IVC filter was placed.

The following 4 cases were associated with patient death.

3. This patient is described in detail in the March 10, 2004 HHE. This morbidly obese patient underwent placement of a Recovery filter prior to bariatric surgery. His postoperative course was marked by prolonged intubation and CHF. On day 5 he collapsed while on the toilet and could not be resuscitated. A very large thromboembolus (10 cm x 4 cm) was noted in the R atrium, en-

casing the filter. The cause of death was ascribed to circulatory collapse due to the large thrombus in the R atrium.

4. This patient is described in detail in the April 27, 2004 HHE. This patient developed DVT during hospitalization for a subarachnoid hemorrhage. A Recovery filter was placed just prior to discharge from the hospital. On day 13 after placement, the patient was found dead in bed at home. Large thromboemboli were found encasing the filter and attached to the R ventricular wall. There was evidence that the filter struts had pierced the R ventricular wall. The IVC, which measured about 25 mm at insertion, was noted to be 30-35 mm at autopsy.
5. A Recovery filter was placed pre-operatively in a patient who underwent Vertical Gastric Bypass surgery. He had a history of venous thromboembolism associated with bedrest after trauma surgery in the past. About 1 month after surgery, he presented to the ED with vomiting and abdominal pain. RBBB was noted on EKG and his platelet count was 8,000/μL. The patient became hypotensive and attempts at resuscitation were unsuccessful. Autopsy revealed a very large thrombus across the tricuspid valve. It encased the filter, which was partially embedded in the myocardium. Ventricular wall hemorrhage and hemopericardium were seen posteriorly.
6. A Recovery filter was placed in a patient with head trauma. Ten days later, cardiac arrest occurred. The filter was found encased in a large thrombus which had embolized to the R ventricle. Large thrombi were seen from the R femoral vein to the R atrium.

Human Exposure to the Problem: Migration is a known complication of vena cava filter placement. The literature lists its occurrence in about 2% to 5% of patients. However, the literature reports are not clear regarding the incidence of filter migration with or without thrombus.

General Consequences: As seen in the cases reported here, filter migration can lead to minimal or no complications. However, filter migration to the heart is generally symptomatic and can be fatal.

Population Exposed to the Risk: All patients in whom a vena cava filter is placed are at risk for this complication.

Mitigating/Predisposing Factors in the Population at Risk: One discernible predisposing factor for filter migration would be incorrect deployment, including improper location, tilting of the filter or placement in a patient with an IVC too large for the filter (> 28 mm in the case of the Recovery filter). There was evidence of mis-deployment in only 2 of 12 reports of migration, but none in those cases associated with thrombus and patient death. Because of the risks of IVC filters, physicians are careful to place them only in patients judged to be at high risk of symptomatic venous thromboembolism, especially those at risk for fatal pulmonary embolism. Patients with head trauma, morbid obesity are at particularly high risk of venous thromboembolic disease. The risk of pulmonary embolism in the types of patients reported on in this HHE is judged to be in the range of 0.5% to 12%, despite the use of other antithrombotic modalities such as compression stockings or anticoagulation. In addition, IVC filters are the best option to lower the risk of fatal PE in many patients in whom anticoagulation cannot be given due to head injury or major bleeding.

A second predisposing factor for migration would be the development of a large burden of thrombus. Analysis of the reports of Recovery filter migration shows that all occurred in patients with proven large thrombi; no cases of (non-iatrogenic) filter migration alone have been seen. Thus, patients in whom the Recovery filter is most likely to be life-saving, i.e., those at high risk of developing fatal PE due to large thrombi, are most predisposed to this complication. It is pertinent to note that these patients would likely have been at considerable risk of dying from their emboli whether or not the Recovery filter was present. Also, in those cases in which migration was confined to the IVC, the Recovery filter probably played an important role in preventing pulmonary embolism.

Nature & Seriousness of the Risk: The effect of migration, as mentioned above, may be no discernible effect to sudden death.

Likelihood of Occurrence of the Problem: Review of the literature reveals a risk of filter migration in the range of a few percent. However, there are no controlled trials to answer this question definitively. Review of MDR reports for all filters in the MAUDE database, in conjunction with estimates of the number of filter placements, places the rate of migration in the range of 0.02 -0.15%. Another manufacturer of retrieval filters reports a rate of 0.02% (source: Günther Tulip vena cava filter IFU). However, reliable comparability data for this complication across manufacturers are not available due to the inherent subjectivity in reporting practices. There have been 10 cases of migration reported for the Recovery filter, and about 10,000 filters have been placed, giving a migration rate of approximately 0.1%. The rate of potentially life-threatening injuries associated with this hazard is 5 in 10,000 (0.05%, based on the 4 fatalities and 1 patient with renal vein thrombosis) and fatality rate due to this complication is approximately 4 per 10,000, or 0.04%. As discussed above, it is likely that fatalities due to PE would have occurred in some or all of these cases in the absence of the Recovery filter.

Likelihood of Harm if the Problem Occurs: Filter migration to the heart, with or without thrombus, is likely to cause serious injury, if only in the requirement for surgery to retrieve the filter. Filter encased in a large thrombus might present a higher risk than thrombus alone, based on the cases where the filter struts were reported to have pierced the ventricle. However, it is not possible to separate the effects of the large thromboembolus from the effects of the filter alone.

Is the Product Essential to Health: Yes. It is particularly important in patients at high risk of thromboembolism for whom anticoagulation if contraindicated or ineffective (about 20% or more of patients).

Is there an Alternative Available: Yes. Alternative IVC filters exist, but the ability to retrieve the Recovery filter in patients with transient risk of venous thromboembolism makes it an important treatment option for many patients.

Must the Problem Device be Removed or Corrected Surgically: Yes

Is the Problem Expected & Within an Acceptable Statistical Range: Yes, to the extent that comparative data are available.

Can the Problem be Corrected in the Field: Percutaneous retrieval of a migrated Recovery filter is sometimes possible, leading to correction/mitigation of the migration risk. However, when the filter is encased in thrombus, percutaneous retrievable may be impossible or contraindicated.

Is the Problem or Health Hazard Obvious to the User: As mentioned above, filter migration is a known complication of IVC filter placement. However, there is no way to predict which patients will develop this complication. Reported cases involved patients with varying diagnoses at very high risk for venous thromboembolism; that is the reason for placement of the filter. There were no major procedural problems reported in the 10 patients with thrombus, and vena cava size was within the range recommended by the Recovery Filter System IFU.

Can the Product Continue to be Used with Proper Warnings: Yes.

Is the Device Used Only by Specially Trained Health Care Professionals: Yes.

EXHIBIT 47

From: Hudnall, Janet [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=JHUDNALL]
Date: 7/15/2004 11:24:56 PM
To: TPE-Interventional Sales-DG [/O=BARD/OU=MHL AG/cn=Recipients/cn=TPE-InterventionalSales-DG], Coutanche, Monica [/O=BARD/OU=MHL AG/cn=Recipients/cn=MCoutanche], Lawson, Matthew [/O=BARD/OU=SYD AG/cn=Recipients/cn=MLawson], Ruggiero, Roberto [/O=BARD/OU=ROM AG/cn=Recipients/cn=RRuggiero], Borremans, Frank [/O=BARD/OU=OLN AG/cn=Recipients/cn=FBorremans]
CC: McDermott, John [John.McDermott@crbard.com], Shifrin, Kevin [Kevin.Shifrin@crbard.com], Edwards, Mary [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=MEdwards], Uelmen, Doug [Doug.Uelmen@crbard.com], Carr, Robert [Robert.Carr@crbard.com], DeCant, Len [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=LDeCant]
Subject: Vena Cava Filter Complications Q&A
Attachments: Vena Cava Filter Complications 3.doc

All,

Attached is a document that details some frequently asked questions regarding Recovery complications. This document contains verbiage that has been corporate-reviewed and approved. Please do not deviate from this script and please do not distribute--this document is strictly for internal use only.

Please feel free to contact me with any questions/concerns.

Regards,
Janet

Vena Cava Filter Complications – FAQs

Q: What is the migration rate for Recovery® Filter?

A: It is difficult to determine actual rates. Acceptable statistical ranges cannot be reliably calculated from available data. However, estimates based on MAUDE and sales data suggest that there is no significant difference in the rates of these complications between competitive devices, including the Recovery® Filter.

The following table shows the number of incidents reported to the MAUDE database for period beginning Q2, 2003 through Q2,2004:

Complication Type	Recovery	Total for All Filters (includes Recovery)
Migration	9	39
Central Migration (Subset of Migration)	7	23
Caval Penetration	1	2
Caval Perforation	0	12
Caval Thrombosis	0	10
PE	4	5
Filter Fracture	1	13
Death	5	16

Reporting period: April 2003 - June 2004

Q: What were the circumstances surrounding the deaths?

A: In all cases of migration-related deaths, the filter was reportedly placed appropriately; however, a massive thrombus burden overwhelmed the filter. The diameter of the thrombus distended the vena cava to the point where its diameter exceeded the physical limits of the filter.

Q: Why did the new complaints not prompt a product hold?

A: The initial hold was an internal action. The FDA was never involved in the decision to put the product on hold. It was a conservative step that allowed us the time to determine if our overall complication rates were comparable to those reported in the literature and the MAUDE database for other IVC filters.

Every reported complication is treated with the utmost care and seriousness. Although the new reported migrations are unfortunate, they still fall within our expected parameters.

Q: Why didn't you tell us about the complications before the MAUDE database update?

A: It is inappropriate to discuss reported complications prior to the completion of the investigation. For each case reported, we conduct a thorough investigation according to our established, systematic process which can take a great deal of time and resources.

Q: Is Recovery® Filter a safe device?

A: The Recovery Filter was rigorously tested for all physical performance characteristics according to our established test methods and protocols and was found to meet all test specifications and requirements.

As stated previously, Recovery® Filter's overall complication rates are comparable to those reported in the literature and the MAUDE database for other IVC filters.

EXHIBIT 49

Internal Q&A: CR Bard Recovery® Vena Cava Filter
Version Aug. 30, 2004

Note: Internal Q&A to be used by approved Corporate spokespeople to respond consistently to inquiries from media. Not to be handed out externally to any audiences.

1. *What is the* Recovery® *Vena Cava Filter and how does it work?*

   Introduced in April 2003, the Recovery® Nitinol Vena Cava Filter is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC). The Recovery® Filter has the additional feature, which was approved in July 2003, of being able to be percutaneously removed after implantation. The Recovery® Filter may be used as a permanent or temporary device.

   The Recovery® Filter System consists of the Filter and Delivery System. The Filter consists of twelve nitinol wires emanating from a central sleeve. These twelve wires form two levels of filtration. The device is intended to be used in the (or vena cavae)vena cava with diameters of up to 28 mm (in isolation the 28 mm value means nothing. Wouldn't we want to say : in selected patients who may benefit , or in patients who meet the criteria, as judged by his/her physician, set in our IFU . What is the important point here?

2. *What is the difference between a retrievable vena cava filter and a non-retrievable vena cava filter?*

   A non-retrievable vena cava filter is indicated for permanent use; once inserted into the vena cava, the device is left in place. This begs the question somewhat. A permanent filter is one that CANNOT be safely removed; my guess is that physicians would like the option of easy and safe filter removal for ALL filters they implant. On the other hand, after implantation, a retrievable vena cava filter may be removed at the physician's discretion, once the risk of a venous thromboembolism or pulmonary embolism is reduced or if the side effects of the filter make removal advisable.

   The Recovery® Filter is designed to act as a permanent filter. When clinically indicated, the Recovery® Filter may be percutaneously removed. The Recovery® Filter's hooks allow the filter to remain rigid and provide anchoring, but deform when the filter apex is engaged with the specially

designed removal device (Recovery Cone® Removal System) and pulled upward.

3. *What is the marketshare of the Recovery® Filter for the overall vena cava filter market?*

   Less than 10% (in units).

4. *What is the marketshare of the Recovery® Filter for the retrievable vena cava filter market?*

   Our sales are approaching 14,000 units of the Recovery® Filter. We understand that the overall total market worldwide?for all retrievable and non-retrievable vena cava filters is approximately 130,000 units.

   While the retrievable segment of the vena cava filter market is rapidly growing, for the past 12-month period, the market is estimated to have been approximately 30,000 units. Of that, Recovery® had a 25% share.

5. *How many Recovery® Vena Cava Filters have been inserted in the US and, separately, around the world?*

   As of August 2004, our sales are approaching 14,000 units of the Recovery® Filter.

6. *Do you have any studies that prove the safety and efficacy of the Recovery® Vena Cava Filter?*

   Yes, we have studies that prove this is a difficult word here. Proving safety is a hard thing to do with any degree of certainty, and we don't have the large scale controlled clinical studies that most educated individuals and physicians would accept as eveidence of "proof". the safety and efficacy of the Recovery® Vena Cava Filter. For example, the Recovery® Filter was safely and effectively used in a study at six Toronto area hospitals. In this Toronto study, of the 58 filters implanted, a total of 46 have been retrieved to date. If this is for internal questions, would we not want to comment on the complaint data – surely it is relevant to any discussion of "safety and efficacy"

   In addition, the Recovery® Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

   We are happy to provide a full listing of study summaries to you.

7. *What are pulmonary emboli and what are the risks associated with them?*

Pulmonary emboli are blood clots that form in large veins, such as those in the thigh, and then travel to the lungs. In the lungs, they block blood flow, which can cause shortness of breath, chest pain, faintness, low blood pressure, lung damage, and in severe cases, sudden death. Such clots are particularly likely to form in a variety of unusual circumstances, including prolonged immobility, after hip surgery, after major traumatic do you mean trauma surgery or any major surgery? surgery and in obese individuals after weight reduction ("bariatric") surgery.

8. *Under what circumstances would the Recovery® Vena Cava Filter be used?*

The Recovery® Filter is indicated for use in the prevention of recurrent pulmonary embolism through permanent or temporary placement in the vena cava in the following situations:

a. Pulmonary thromboembolism when anticoagulants are contraindicated.
b. Failure of anticoagulant therapy for thromboembolic disease.
c. Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
d. Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The device is intended to be used in vena cavae with diameters of up to 28 mm, and when clinically indicated, the Recovery® Filter may be percutaneously removed. this is redundany with clinically indicated.

9. *How is the Recovery® Vena Cava Filter inserted?*

The Recovery® Vena Cava Filter is inserted into via (or into a femoral vein) a femoral venous access route during a procedure performed by a medical professional. The "Instructions for Use" provide more information about the insertion and removal procedures.

10. *Who designed the Recovery® Filter?*

Bard purchased the product design and manufacturing from a valued partner. Bard has thoroughly assessed and tested the product and stands behind its design in every way.

11. *What is the name of the company that designed the Recovery® Filter?*

That information can be found in public records.

12. *Have there been any design changes in the Recovery® Filter over the years?*

The designs of our products are updated periodically as part of our commitment to continuous improvement. In the case of the Recovery® Filter, there have been changes in the delivery system but not the filter itself.

13. *What level of expertise is required to properly insert the Recovery® Vena Cava filter?*

Physicians who have undergone training for minimally invasive, endovascular procedures can place the Recovery® Vena Cava Filter. These physician specialties include, but are not limited to, interventional radiologists, vascular surgeons, trauma surgeons, cardiologists, and general surgeons as well as residents and fellows of those disciplines.

Placement of the Recovery® Filter, in general, is quick (10 minutes) if there is easy access to the femoral vein. The procedure has been described by physicians as easy to perform.

14. *How are doctors trained on the proper use of the Recovery® Vena Cava filter? How extensive is this training?*

There is currently no formal training requirement imposed on users by Bard for filter *insertion*.

Filter *retrieval* is under a limited market release process which requires the user to either 1) attend a one-day hands-on workshop or 2) have a qualified sales representative present for their cases.

To our knowledge, other makers of retrievable filters do not require physician training for filter insertion and/or removal.

15. *What are the potential complications associated with the Recovery® Vena Cava filter?*

Potential complications observed for all types of inferior vena cava filters including the Recovery® Filter include filter migration, perforation of the vena cava wall by filter legs, and vena caval occlusion or obstruction. Fractures and fracture/migration events?

16. *How often does the Recovery® Filter actually migrate?*

As of the end of August 2004, our sales are approaching 14,000 units of the Recovery® Filter. Of this number, there have been 16 reported cases of migration since 2000.

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other competitive products.

There is risk of migration with any vena cava filter. There is no single definitive cause of filter migration. The buildup of a large clot or series of clots, the movement of the walls of the vena cava due to respiration and improper filter placement are all likely causes of filter migration. There are also other factors that could potentially cause a filter to migrate, and many questions still remain as to exactly why filters migrate. In addition, filters may appear to have migrated due to x-ray equipment variation, patient position, measurement error, and respiration.

17. *How does your rate of migration for the Recovery® Filter compare to that of your retrievable and nonretrievable device competitors?*

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other competitive products.

18. *Are retrievable filters more susceptible to migration than non-retrievable filters?*

Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other competitive products.

19. What causes filter migration?

Filter migration occurs whenever the force trying to move the filter exceeds the holding power of its fixation arms. A properly placed vena cava filter can constrain a significant amount of blood clot, but large blood clots can overwhelm the filter's retentive capabilities. Other recognized causes of filter migration include improper implantation technique, unusual patient exertion (such as straining at bowel movements) and fracture or failure of the filter wires. All marketed filters in the US have reported instances of filter migration.

It also is important to point out that the exact reason/mechanism of filter migration has not been described in medical literature. In other words, no one knows for sure how/why filters migrate.

20. What is the "acceptable" rate of migration for vena cava filters?

Realistically, migrations do occur. All marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter.

Additionally, the removability of the filter permits its use in an expanded population. For example, in the past, there were no acceptable options – a filter would not be placed in young people, some trauma patients, and patients who were contraindicated for anticoagulants.

Now, these patients have the choice of having a filter placed because it is removable.

21. What are the dangers associated with filter migration?

Some filter migrations are harmless to the patient and include filter movement of a few centimeters. In unusual cases, a filter containing a large amount of clot may migrate through the bloodstream to the lungs or heart. These complications can require surgical removal of the filter and clot, and rarely cause death. Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

22. *If a retrievable filter provides the added benefit of retrievability and creates no greater risk of migration or other complications, why would any physician choose to use a non-retrievable filter?*

I cannot speak on behalf of physicians but understand that non-retrievable filters can be less expensive than retrievable filters. Presumably, if a physician believes there will be no reason to remove the filter, it might make sense to choose the less expensive non-retrievable option. However, there is no way to predict with 100% accuracy whether or not a patient is going to require the filter for the rest of his/her life. I understand though, that an increasing number of physicians choose retrievable over non-retrievable vena cava devices after gaining greater understanding of the safety, efficacy and added benefits of retrievable filters.

23. *Migration of a Recovery® Filter was recently listed as the cause of death for a patient in [redacted] FL. Can you tell us why this specific filter migrated?*

As with any report of an adverse event, we took an immediate, systematic approach to determine the cause and events. We formed a multi-disciplinary team to thoroughly investigate the incident. From the information available to date, we have drawn the following conclusions regarding the role of the Recovery® Filter in this event:

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Patients with morbid obesity who undego bariatric surgery are at increased risk of blood clots and pulmonary emboli..

Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

24. If filter migration was not the cause of death, why was it listed as the cause of death on the coroner's report?

I cannot speak for the coroner. What I can tell you at this point, however, is that from the information available to date, no conclusions can yet be drawn regarding the role of the Recovery® Filter in this event.

We do know that there was a very large blood clot or an accumulation of blood clots, measuring 10 cm in length and 3 cm in diameter, which deposited around the filter over a period of several days. The large blood clot or accumulated clots may have enveloped the filter and traveled through the bloodstream to the patient's heart, causing sudden death. The patient was morbidly obese but we are unsure whether this caused any health conditions. Morbid obesity can contribute to the formation of blood clots.(as above)

Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

25. Is it possible that the filter was not inserted properly?

I will not speculate on the role of filter placement in this incident. What I can say is that, while improper filter insertion or placement can cause migration, we believe a blood clot as large as the one that enveloped the filter in this incident might cause migration of any IVC filter.

Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

26. Is there any reason to believe that the Recovery® Filter is to blame for this patient's death?

I will not speculate on the role of the Recovery® Filter in this incident. What I can say is that we believe a blood clot as large as the one that enveloped the filter in this incident might cause migration of any IVC filter.

Without the filter, this amount of clot would generally have passed directly to the lungs or heart, causing substantial harm on its own.

27. Has Bard been sued by the family of the deceased?

Not to my knowledge.

28. *Migration of a Recovery® Filter was recently listed as the cause of death for a patient in* Redacted *MI. Can you tell us why this specific filter migrated?*

As with any report of an adverse event, let me assure you that we are rigorously investigating this incident and putting our best resources toward understanding the reported migration. With this particular event, we formed a multi-disciplinary team to thoroughly investigate the incident.

[INSERT FINDINGS OF GRAND RAPIDS INVESTIGATION]

29. *Migration of a Recovery® Filter was recently listed as the cause of death for a patient in* Redac ted *MA. Can you tell us why this specific filter migrated?*

As with any report of an adverse event, let me assure you that we are rigorously investigating this incident and putting our best resources toward understanding the reported migration. With this particular event, we formed a multi-disciplinary team to thoroughly investigate the incident. As we learn more definitive information, we will make that information available.

[INSERT ANY NEW AVAILABLE INFORMATION]

30. *Migration of a Recovery® Filter was recently listed as the cause of death for a patient at* Redacted *(MO). Can you tell us why this specific filter migrated?*

As with any report of an adverse event, let me assure you that we are rigorously investigating this incident and putting our best resources toward understanding the reported migration. With this particular event, we formed a multi-disciplinary team to thoroughly investigate the incident. As we learn more definitive information, we will make that information available.

[INSERT ANY NEW AVAILABLE INFORMATION]

31. *Migration of a Recovery® Filter was recently listed as the cause of death for a patient at* Redacted *(OH). Can you tell us why this specific filter migrated?*

As with any report of an adverse event, let me assure you that we are rigorously investigating this incident and putting our best resources toward understanding the reported migration. With this particular event, we formed a multi-disciplinary team to thoroughly investigate the incident. As we learn more definitive information, we will make that information available.

[INSERT ANY NEW AVAILABLE INFORMATION]

32. *Migration of a Recovery® Filter was recently listed as the cause of death for a patient in* Redacte *NJ. Can you tell us why this specific filter migrated?*

This incident was only recently brought to our attention and, as with any adverse event, we are rigorously investigating this incident and putting our best resources toward understanding the reported migration. As we learn more definitive information, we will make that information available.

[INSERT ANY NEW AVAILABLE INFORMATION]

33. *I understand that this was the second migration at this hospital. Was it placed by the same physician? Was it physician error?*

This incident is under full investigation. It is too early to make any conclusions regarding the physician's role in the placement of the filter.

34. *Has Bard placed the product on hold while these reported incidences of migration have been investigated?*

No.

35. *Has the Recovery® Filter been associated with other deaths in the past?*

Yes. A patient in Redact Wisconsin died with a Recovery® Filter in place. The cause of death cited was pulmonary embolism and not related to the Recovery® Filter.

36. Has Bard been sued because of death or damage caused by migration in the past?

Not to my knowledge.

37. In the late 80's, weren't Bard's balloon angioplasty medical devices permanently pulled from the market because of safety issues?

The Recovery® Vena Cava Filter products we are discussing today are considered safe and effective by the medical community and had nothing to do with the situation you mentioned. In the late 1980s, a C.R. Bard subsidiary named USCI manufactured balloon angioplasty catheters, which were taken off the market. The details are well documented. USCI was sold and no individual involved in those incidents is currently with the company. Since then, the entire executive management team has been changed. Today, Bard maintains an excellent working relationship with the FDA.

38. What other Bard products have been pulled from the market and for what reasons?

Bard has been in business for nearly a century, and we are known for our commitment to provide innovative, life-enhancing medical technologies to our patients. Holds can occur for a variety of safety and non-safety related reasons. In cases in which safety was a concern, products were placed back on the market after further testing. The Recovery® Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

39. What Bard products have been put on hold in the past two years?

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery® Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

40. Have you pulled any products over the past five years that have not been put back on the market? If yes, why were they pulled?

As a course of company policy, we do not discuss previous product recalls. When such a recall occurs, we quickly and proactively provide necessary information to impacted customers, physicians and patients. The Recovery® Vena Cava Filter products we are discussing today are considered safe and effective by the medical community.

41. How does Bard receive and respond to reports of adverse events associated with its Recovery® Vena Cava Filter?

With any report of an adverse event, we take an immediate, systematic approach to thoroughly investigate the incident. Our system of tracking and monitoring complaints and adverse events enables us to respond directly to healthcare professionals. We take very seriously our responsibility of developing and delivering safe medical devices.

42. Are there any physicians I can talk with about the safety and efficacy of the Recovery® Vena Cava Filter?

Gary S. Cohen, MD
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3401 N. Broad Street
Philadelphia, PA 19140
(215) 707-3951
cohenator@aol.com

[Janet: Can we include at least one more physician?]

43. Can you explain the data in the FDA's MAUDE database for the Recovery® Filter as compared to other vena cava filters?

The MAUDE database is a quarterly summary of all "MDRs" or "Medical Device Reporting" to the US Food and Drug Administration. It is difficult to use and compare this data for vena cava filters for several reasons, including potential under-reporting and inadequate description of events that could be unrelated to the death or injury, the fact that sales data can only be roughly estimated, and the high variability in event rates across devices and across time periods.

Comparative attempts to assess similar events via the MAUDE database do not yield accurate, quantitative estimates.

44. Since February 2004, there have been six reported deaths associated with the Recovery® Vena Cava Filter. Shouldn't Bard pull this product from the market?

Many of these incidences are still under investigation, and we will not speculate on the role of the Recovery® Filter in these events.

However, you should know that, realistically, migrations do occur; in fact, all marketed filters in the US have reported instances of filter migration. Experts continue to debate what constitutes an acceptable rate of migration, relative to the risk of not using the filter. In our labeling, we clearly caution clinicians of this risk. We have no plans to remove this product from the market.

45. Why did you recently change the labeling on the Recovery® Filter?

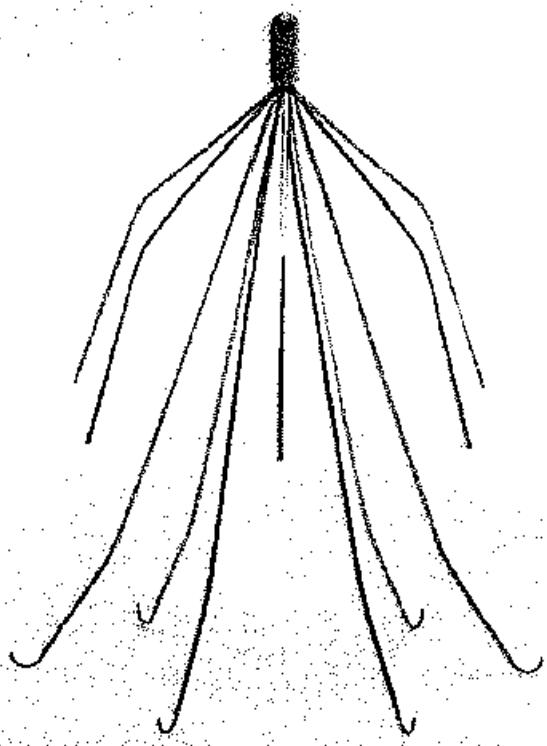
The Recovery® Filter has been on the market one year and we've taken a hard look at the clinical experience with this product. Based on this clinical experience, we have modified the warnings and potential complications – reiterating the potential serious complications associated with the use of this device.

46. Why didn't the previous "Information for Use" (IFU) warn of the possibility of migrations?

Our previous "Information for Use" DID warn of potential for migrations and other potential complications associated with the use of this device. However, after reviewing the clinical experience over the past year, we decided to modify the labeling to be more explicit regarding the possibility of migrations.

EXHIBIT 50

BARD
PERIPHERAL
VASCULAR



RECOVERY

Timeless Performance™

Vena Cava Filter

DESIGNED TO BE THE ONLY FILTER
YOU WILL EVER NEED.

Bard established itself as a leader and innovator in the vena cava filter world with over 100,000 successful filter placements. Now, we have leveraged our decade-long experience to bring you the next-generation in filter performance. Introducing RECOVERY. A marked improvement over currently available devices,

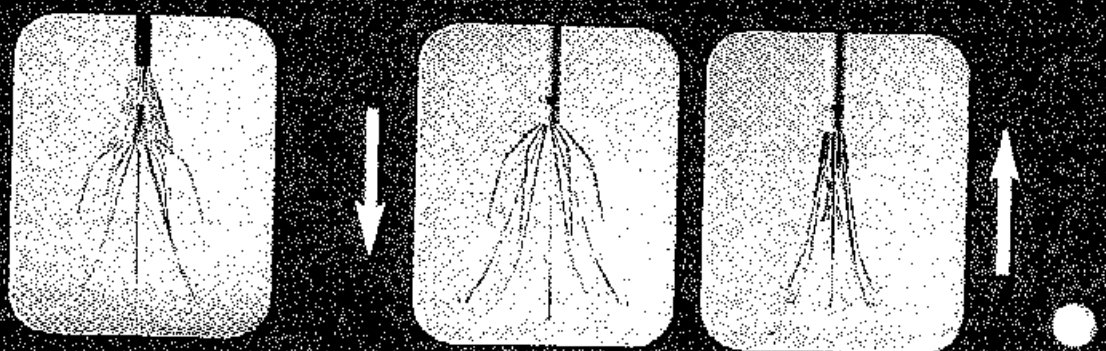
RECOVERY® FILTER SYSTEM

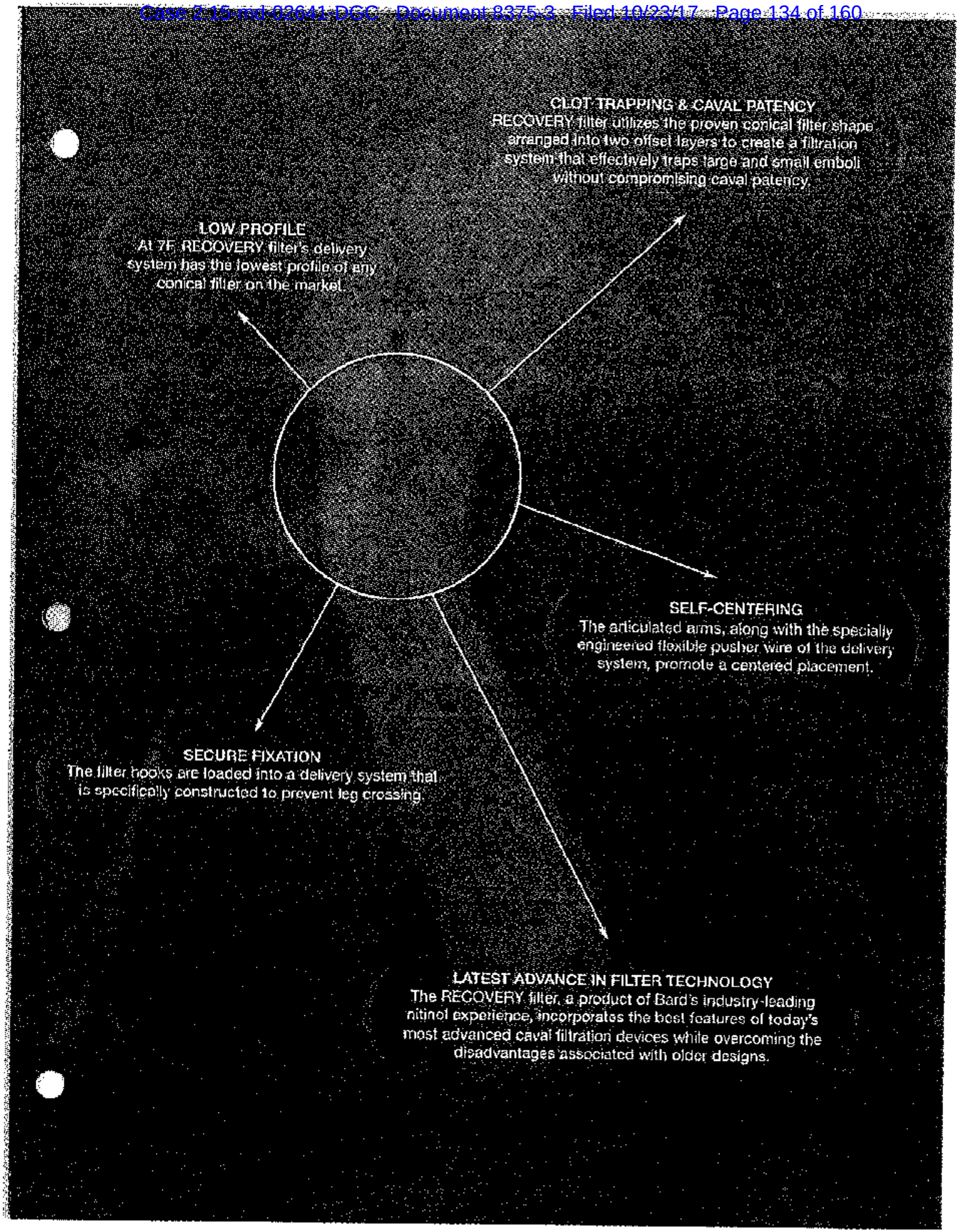
RECOVERY filter's unique self-centering design, proven conical shape and bi-level filtering system create the ideal balance between clot trapping efficiency and caval patency. Advanced design and accurate placement coupled with lasting performance make RECOVERY the permanent solution for caval interruption -- possibly the only filter you will ever need.

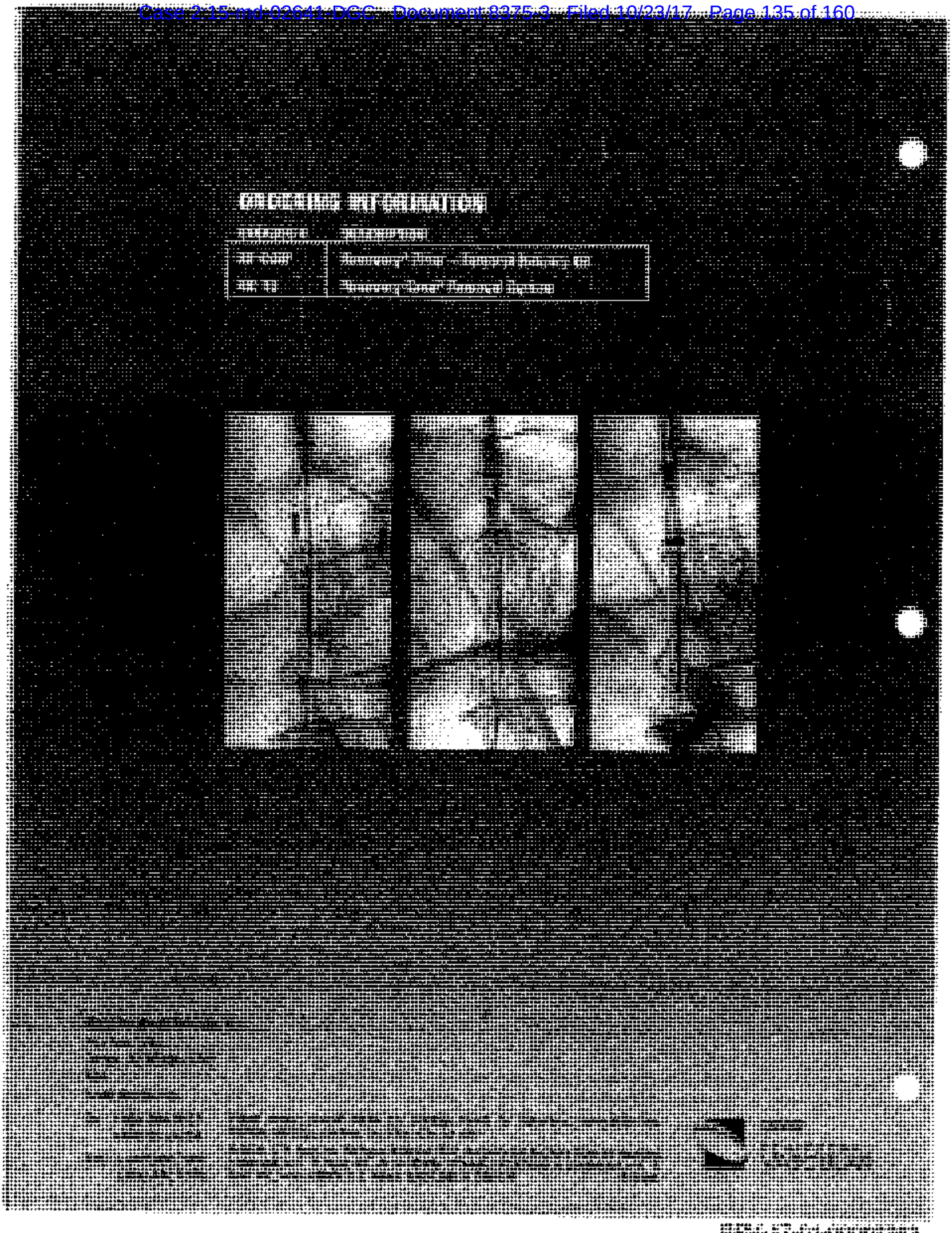
The RECOVERY Cone Removal System was specifically designed to work with the RECOVERY Filter. The advanced engineering that went into developing the filter was

RECOVERY® CONE REMOVAL SYSTEM

used to create a system that provides a safe and easy retrieval, time after time.




CLOT TRAPPING & CAVAL PATENCY
RECOVERY filter utilizes the proven conical filter shape arranged into two offset layers to create a filtration system that effectively traps large and small emboli without compromising caval patency.
LOW PROFILE
At 7F, RECOVERY filter's delivery system has the lowest profile of any conical filter on the market.
SELF-CENTERING
The articulated arms, along with the specially engineered flexible pusher wire of the delivery system, promote a centered placement.
SECURE FIXATION
The filter hooks are loaded into a delivery system that is specifically constructed to prevent leg crossing.
LATEST ADVANCE IN FILTER TECHNOLOGY
The RECOVERY filter, a product of Bard's industry-leading nitinol experience, incorporates the best features of today's most advanced caval filtration devices while overcoming the disadvantages associated with older designs.



LMD1

EXHIBIT 51

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS)
PRODUCTS LIABILITY LITIGATION,) MD-15-02641-PHX-DGC
_____)

DO NOT DISCLOSE - SUBJECT TO FURTHER
CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF JACK SULLIVAN,

produced, sworn and examined on behalf of the Plaintiffs, pursuant to Notice, on Friday, the 16th day of September, 2016, between the hours of 9:08 a.m. and 6:19 p.m. of that day, at the law offices of Wagstaff & Cartmell, LLP, 4740 Grand Avenue, Suite 300, in the City of Kansas City, in the County of Jackson, and the State of Missouri, before me, NAOLA C. VAUGHN, CCR No. 1052, CRR, RPR, a Certified Court Reporter, within and for the State of Missouri.

what it says. This is really blurry.

Q. Well, take your time if you want to -- if you want to try to --

A. Do you have a magnifying glass? Honestly? It's blurry. That's the problem.

Q. I got to be honest, I don't find it very difficult to read. I'm looking at the same thing you are.

A. If you want to read that to me.

Q. Sure. It says, "Movement or migration of the filter is a known complication of vena cava filters."

A. It says more than that; right?

Q. You want the whole thing?

A. I don't . . .

Q. "This may be caused by placement of IVC of diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots, and/or dislodgement due to large clot burdens."

A. Okay. Thank you.

Q. No problem.

A. I don't know if it's my eyes or what.

Q. No problem.

Anything about that that applies to filters differently, or does it just cover vena cava filters generally?

A. I think it's a general warning statement about vena cava filters.

Q. And let's -- just so you can -- I'm going to hand you --

MS. KOWALZYK: This copy isn't a clear copy.

(Exhibit 426 marked.)

Q. BY MR. DeGREEFF: I'm going to hand you what's been marked as Deposition Exhibit 426, or about to be.

MR. DeGREEFF: Maybe we can short circuit a lot of this. It's my understanding Bard has stipulated there's no comparative data in the IFUs; is that right?

MR. NASH: I'm not aware of any.

MS. KOWALZYK: I'm not aware of any stipulation.

MR. DeGREEFF: Okay.

MS. KOWALZYK: Do you want me to -- do you want to move on to something else, and we'll find out on a break?

MR. DeGREEFF: I can do it quick.

Q. BY MR. DeGREEFF: I'm handing you what's been marked as Deposition Exhibit 426, and this is a G2 IFU.

A. Right.

Q. Let's just talk briefly about --

MR. O'CONNOR: Excuse me one second. I have just learned that we are starting -- well, I think I know the last exhibit number was either 425 or we're supposed to start at 425, but I will get a clarification on that, and we'll start from there.

Q. BY MR. DeGREEFF: Okay. My question for this one is on the second page.

A. Yes, sir.

Q. Under Warnings.

A. Okay.

Q. Numbers 5 and 6.

A. Yes.

Q. This contains the same -- my only question is: This contains the same statement about filter fracture and movement or migration is a known complication of vena cava filters?

A. Yes.

Q. And that's the same as the IFU we just

looked at?

A. Looks very similar.

Q. And I don't see -- will you look at the warnings for me. I don't see any mention of tilt.

Is there any mention of tilt in there that you see?

A. Are you specifically looking for the word "tilt"? I guess that's what I need to ask.

Q. Do you have an understanding of what filter tilt is?

A. Yes.

Q. Anything that you think lends itself to filter tilt?

A. It's hard -- I'm not trying to be difficult, but it's hard to say; right? The first sentence is, "Do not deploy the filter prior to the proper positioning in the IFU." So that could lend itself to tilt. Is that right? No?

Q. You tell me.

A. Sounds like it.

Q. You think that's a warning about the risk of a tilt?

A. "Do not deploy the filter prior to proper positioning in the IFU."

yourself, she has to put it down.

THE REPORTER: I'm just putting that you're mumbling because that's what I'm hearing.

THE DEPONENT: Beautiful. My mom would be proud.

A. I think that's all I can see is a movement. Movement could mean tilt.

MR. O'CONNOR: First exhibit should be 425 and then 426. So that's what we should do.

(Exhibit 427 marked.)

Q. BY MR. DeGREEFF: I'm handing you what's going to be marked as -- what?

THE REPORTER: 427.

MR. DeGREEFF: 427.

Q. BY MR. DeGREEFF: Handing you what's been marked as Deposition Exhibit 427. This is the G2X IFU.

Does that appear correct? Or one of the G2X IFUs?

A. It says, yes, IFU for G2.

Q. Again, let's make it pretty quick. If you'll look at the page that discusses warnings.

A. Can you tell me what page it's on?

Q. Yeah. I think -- if you look at the Bates in the bottom, very bottom right-hand

corner.

A. Yeah.

Q. It's 10758.

A. Okay.

Q. And 6 and -- number 6 and 7 of the warnings discuss filter fracture and movement or migration; is that correct?

A. Yes. I -- I'm not trying to be difficult, but this is -- they're not easy to read because they're blurry; right. But it looks to be the same thing.

Q. Yeah. My question's pretty -- was pretty simple. I mean, I'm just going to -- again, this discusses filter fracture as a known complication of vena cava filters; right?

A. Yes. Looks like that's what it says.

Q. And that relates to all vena cava filters?

A. Yes.

Q. And, again, the -- this time it says tilt. "Movement, migration, or tilt of the filter are known complications of vena cava filters."

Right?

A. Okay. Yes.

Q. And, again, that relates to all

filters?

A. Yeah. It's kind of broad. It says all filters -- of vena cava filters as a statement. Yeah.

(Exhibit 428 marked.)

Q. BY MR. DeGREEFF: Okay. Sir, I'm handing you what I marked as -- or what I'm going to mark as 420 -- Deposition Exhibit 428.

I'll ask you a few questions about this one.

This document is the titled, Internal Q&A: CR Bard Recovery Vena Cava Filters, Version August 30, 2004; correct?

A. Yes.

Q. And is this -- and it states in that note that it's a -- that it's approved by -- it's to be used by approved corporate spokespeople to respond to inquiries from the media; right?

A. Yes.

Q. Not to be -- so is this something that you, in your role at the company, would have ever seen?

A. I don't recall having ever seen this document, no.

Q. Okay. Have you ever seen anything

like this? Did you receive these internal Q&As?

A. Specifically about answering questions from the media, no, I never did.

Q. Okay. Look at -- look at page 4, if you would, number 10.

A. Okay.

Q. There's a question about who designed the Recovery filter, and the answer is -- the second sentence says that "Bard has thoroughly assessed and tested the product and stands behind its design in every way."

Did I read that correctly?

A. Yes. That's what it says.

Q. Was that something that was a message that was presented by the salespeople to physicians, that the devices were properly tested and thoroughly tested?

A. Sure. Yeah.

Q. Would you expect before a -- as a salesperson, would you expect a product to be properly and thoroughly tested before it ends up in patients?

A. I would -- sure. My expectation would be and I think anyone's expectation would be that it met all criteria that the FDA would stipulate

tape number 2. It's 10:19 a.m. We're back on the record.

Q. BY MR. DeGREEFF: Sir, you've had a -- we've taken a break. In fairness to you, did you have a chance to meet with counsel?

MS. KOWALZYK: Object to the form.

A. Well, we talked, walking to the restroom. Right.

Q. BY MR. DeGREEFF: Having spoken to her now, is there anything about your testimony thus far that you want to change?

A. No, sir.

Q. Okay. So would you -- let's look at page 6 of Exhibit 428.

A. Yes. I'm there.

Q. And number 17, the question is: "How does your rate of migration for Recovery filter compare to that of your retrievable and non-retrievable device competitor's?"

And then the response that's supposed to go in response to the media is: "Estimates based on available data suggest that these types of events are not occurring with excess frequency when compared with other competitive products."

Did I read that correctly?

A. Yes.
Q. And is that consistent with what -- what you understood during your time there?
A. I would -- I would have to -- I don't recall how -- I don't want to keep saying that to you that it was a long time ago.
But I would -- I would believe that, yes.
Q. And this is a -- these are questions and answers for the media; correct?
MS. KOWALZYK: Object to the form.
A. Yeah. Yeah. If -- for a corporate spokesperson to respond to the media, yeah.
Q. BY MR. DeGREEFF: So in other words, this is what the corporate spokesperson is going to tell the public?
A. Yes.
Q. And the public would include physicians?
A. Sure.
Q. And it would include patients?
A. Yes.
Q. And is this -- is this generally something that would have been -- strike that.
Is this consistent with your

understanding of what the IFU said?

MS. KOWALZYK: Object to the form.

A. Talking about migration, I think the IFU -- I don't have it in front of me, but it said migration, something along the lines, is a known complication for all filters.

Q. BY MR. DeGREEFF: Correct.

A. So I guess that would be consistent. That would mean they're all pretty comparable.

Q. And so that is what -- that is what would have been conveyed to the sales force by Bard; is that fair?

MS. KOWALZYK: Object to the form.

A. Yes.

Q. BY MR. DeGREEFF: Okay. And is that what the sales force would have then conveyed to the physicians in response to any questioning about migration rates with the Recovery?

MS. KOWALZYK: Object to the form.

A. Yes.

Q. BY MR. DeGREEFF: And then the next question, number 18, is: "Are retrievable filters more susceptible to migration than non-retrievable filters?"

Did I read that correctly?

A. Yes.

Q. Is it something that you would have wanted the sales force working for you to be using?

A. Yes. I think -- you know, sometimes they're left as leave-behinds, and generally physicians don't read brochures. It's best to use them in a conversation, in my opinion.

Q. Okay. So you want your -- would you want your sales force to convey the information in the brochure to the physician?

A. Sure. Ideally, yes.

Q. Okay. And look at page 2, if you would.

A. Okay.

Q. I guess the third sentence down, it says, "Introducing Recovery. A marked improvement over currently available devices."

A. Um-hum.

Q. Did I read that correctly?

A. Yes.

Q. What were the currently available devices at the time that the Recovery was there?

A. So there would have been -- our filter, Simon Nitinol. Cook had a filter. I

think just one. The Bird's Nest filter. Boston Scientific had a filter. I think just one. I can't recall if they had more than one. And VenaTech, I think, had one or two filters.

Q. And this was saying -- this is representing that those are a marked -- that the Recovery filter is a marked improvement over those devices; right?

A. Yes.

Q. And those devices would include the Simon Nitinol?

A. Yes.

Q. And then if you read the next part down, it says Recovery -- excuse me. It says, "Recovery filter's unique self-centering design."

Did I read that correctly?

A. Yes.

Q. And is the -- what is the point of that statement?

MS. KOWALZYK: Object to the form.

A. The point of that statement -- it would not be difficult, but was to call out that it had a unique self-centering design; right.

Q. BY MR. DeGREEFF: Was the idea that it would -- that it was less prone to tilt or move?

MS. KOWALZYK: Object to the form.

A. That was my recollection is that it -- unlike -- for instance, at the time I think Greenfield may have been the predicate, the kind of market leader. And the arms, the upper tier arms on the Recovery kind of would have served as self-center versus a Greenfield which could tilt -- had a propensity to tilt.

Q. BY MR. DeGREEFF: And so if it's a unique self-centering design, that would mean that the Simon Nitinol didn't have it either?

A. Simon Nitinol was a different design. So --

Q. Okay.

A. -- yes.

Q. So this was supposed to -- the idea here was that you wanted doctors to understand that this was going to be more likely to stay centered; is that fair?

A. Well, it would -- yes. I guess you could say that, sure.

Q. And then if you'll look at the next page, there's a part that says, "Self-centering, the articulated arms, along with the specifically engineered flexible pusher wire of the delivery

system, promote a centered placement."

Did I read that correctly?

A. Yes.

Q. So, again, the idea -- was the idea that the -- you know, the -- this device was -- is better at staying centered?

A. But the delivery system, as I recall, and having read this, it kind of harkens me back, that as you're deploying a vena cava filter, the wire in the catheter will always rest on the cava wall. You can't center a wire in a catheter. So it would rest on the wall.

And this device, when you deployed that top tier, would move it over to the center of the cava. So that was a unique design for Recovery.

Q. So the idea is that it -- the centering was -- centering was better with this device?

A. Sure. That it was designed to center, that's for sure.

(Exhibit 431 marked.)

Q. BY MR. DeGREEFF: Okay. So this is Exhibit 431. Sir, I'm handing you what's been marked as Deposition Exhibit 431.

were selling these filters; right?

A. Yes.

Q. So as the person who were overseeing a group of people from Bard selling this filter, you don't have an understanding of what filter they made design changes to get to the G2?

MS. KOWALZYK: Object to the form.

A. I guess to be -- to answer your question fairly and to be clear, it was 12 years ago. I don't -- at that time I may have known. Right now I don't recall.

But you're asking me specifically about that sentence, and it refers to a data on file. So that's all -- I'm kind of just going by what it says here.

Q. BY MR. DeGREEFF: The idea being conveyed to doctors here was that this filter somehow has an enhanced resistance to fracture; right?

A. Yes.

Q. So it's telling physicians that it's more fracture resistant?

A. And fractures were a known complication for vena cava filters.

Q. Okay. But it's -- this is saying it's

some somehow more fracture resistant, enhanced; right?

A. Saying it's enhanced; right.

Q. And it's also saying it has got increased migration resistance; right?

A. Yes.

Q. So it's more migration resistant?

A. Yes.

(Exhibit 432 marked.)

Q. BY MR. DeGREEFF: All right. I'm handing you what I'm marking as Deposition Exhibit 432.

MS. KOWALZYK: Thank you.

Q. BY MR. DeGREEFF: And this was the -- it looks like the approval -- and I will make it easier on you. If you look at the next page, because that one's kind of confusing --

A. Okay.

Q. -- this is an email from Mary Edwards to several people; is that correct?

A. Yes.

Q. And on there is Joe DeJohn.

That would have been your report, the person you reported to in February 2004; is that right?

the intensive training at the national sales meeting."

What's the national sales meeting?

A. So I can't remember at this time if we had two a year or one a year, but every year at the end of the year we had a meeting, gathered the sales team up, celebrate the previous year, do training, product launches, et cetera, at that meeting.

Q. So would you have -- would the Recovery filter have been addressed at the national sales meeting?

A. I would assume it was. It says so, yeah.

Q. And then the next sentence says, "We did test and validate the Recovery filter design in terms of migration resistance."

A. Yes.

Q. "We tested it against the Simon Nitinol filter and found it performed just as well as the SNF in terms of migration resistance - as well as all other measures of filter efficacy. All tests were conducted using our standard test and acceptance criteria."

Did I read that correctly?

A. Yes.
Q. So is this -- this is an email that was going out to the sales force; right?
A. Yes.
Q. And the sales -- the sales force -- is this being provided so that the sales force can answer questions from physicians?
MS. KOWALZYK: Object to the form.
A. I don't know what the goal of it was. If I can -- I don't remember the email. Can I look it over real quick just to see what it says --
Q. BY MR. DeGREEFF: Absolutely.
A. -- if it states its purpose?
Q. Absolutely.
A. So it looks like there was also some articles attached to it, and Janet is making the field -- making it known to the field that there was an incident involving a filter migration.
So there was -- I don't remember at the time what would have necessitated this -- this email other than to say I don't recall when the first migration was. I remember when -- I kind of remember when it happened. It was a big event. So -- because it was a complication, that was a

A. Could be.

Q. Next, filter limb detached and was found in the patient's heart.

That's a serious injury; right?

A. Yes.

MS. KOWALZYK: Object to the form.

A. It could be. Again, these are -- you're asking me -- so at this time I was a regional sales manager, and I -- I'm certain -- and I'm going to have to -- you're asking me a lot of questions about medicine that I can't tell you.

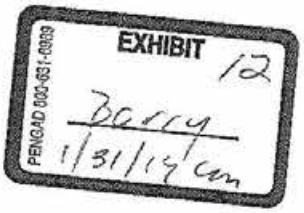
Doctors put stints in hearts. So this was certainly not an ideal thing for the filter to have a leg in someone's heart. And I'm not coarse in saying that it wasn't. I would not want -- I would never want a vena cava filter. I don't want anyone in my family to have one, because you have a lot of sickness that's leading to that.

What I will -- just -- what I don't know by reading this is the filter was tilted at 90 degrees.

Q. BY MR. O'CONNOR: Right.

A. Did it get tilted when the physician was trying to retrieve it? These are things we don't know.

EXHIBIT 54



To: T. Ring/J. Weiland

From: C. Ganser

Date: April 19, 2005

Subject: IVC Recovery Filter Adverse Events (Migrations/Fractures) – Executive Summary

Following is an adverse event summary of the Bard IVC Recovery Filter for migrations and fractures through 4/15/2005:

Migrations

- 34 filter migrations reported > 2 cm
- 21/34 cases involved migration of the filter encased in large thrombi
- 10/21 migrations with thrombi encasement migrated to the heart
- 9/34 migrations - involved morbidly obese/gastric bypass patients
- 8/9 placements in gastric bypass patients occurred preoperatively.
- 9/34 migrations - death reported
- 6/9 migration fatalities - massive clot burden reported to have overwhelmed the filter
- 5/9 migration fatalities - involved morbidly obese/gastric bypass patients
- 1/9 migration fatalities - involved woman suffering from a sub-arachnoid hemorrhage
- 1/9 migration fatalities - involved trauma patient (massive head wound)
- 1/9 migration fatalities - involved a patient post Achilles tendon surgery
- 1/9 migration fatalities - investigation revealed insufficient data
- 5 pulmonary embolism fatalities, unrelated to migration
- 27,166 units sold as of 4/15/2005
- Estimated 21,733 units placed
- Bard IVC Recovery filter migration rate 0.125% (based on units sold)
- Bard IVC Recovery filter migration related mortality rate 0.033% (based on units sold)

Comparative MAUDE/IMS data for IVC filter fatalities (through Q4 2004):

Rates	Fatalities	Migration
SNF	0.000%	0.003%
Recovery	0.041%	0.099%
Vena Tech	0.007%	0.055%
Greenfield	0.008%	0.023%
Bird's Nest	0.015%	0.030%
Tulip	0.013%	0.033%
TrapEase	0.012%	0.012%
OptEase	0.029%	0.010%

MAUDE Fatalities are associated with reports of migration, caval perforation, caval thrombis, PE, and failed deployment.

Fractures

- 51 reports of filter fractures have been reported to date (rate of 0.188%)
- 18/51 cases involved fragments migrated to the heart/lung (0.066%)
- 1/51 fractures - the patient developed serious symptoms requiring open heart surgery to correct/remove
- 2/51 fractures - the patient required a sternotomy to remove a wire two months after filter removal
- No other injuries have been reported
- A literature review reveals that filter fracture is a known complication of IVC filters, with reported rates in the range of 0.05% - 10%